Home interventions and light therapy for the treatment of vitiligo (HI-Light Vitiligo Trial): Health Economic Analysis Plan

Content:

Section 1: Administrative Information

1.1 Title: Home interventions and light therapy for the treatment of vitiligo (HI-Light Vitiligo Trial): Health Economic Analysis Plan

1.2 Trial registration number: ISRCTN17160087

1.3 Source of funding:

This trial is independent research funded by the National Institute for Health Research (NIHR) under its Health Technology Assessment Programme (project number 12/24/02). The pilot RCT was funded by the National Institute for Health Research (NIHR) under its programme grants for applied research (RP-PG-0407-10177). The HI-Light Vitiligo Trial purchased the devices from Dermfix at a discounted rate. Dermfix assisted in sourcing dummy devices for the trial and in arranging logistics of supply, but have had no input into the design or conduct of the trial. The UK Dermatology Clinical Trials Network receive infrastructure funding from the British Association of Dermatologists

1.4 Purpose of HEAP:

This document will outline the methods to be used in the economic evaluation to be conducted alongside the HI-Light Trial, including how data will be collected, analysed and reported. It will be finalised and reviewed prior to the trial database being locked. This HEAP has been written in line with the trial protocol and SAP in order to ensure there is consistency.

1.5 Trial protocol version*:*

This document has been written based on information contained in the trial protocol version 4, dated 3rd March 2017.

1.6 Trial statistical analysis plan (SAP) version

SAP version: , Date:

1.7 Trial HEAP version

HEAP version: 1.0, Date: 29th June 2018

1.8 HEAP revisions

Protocol Version	Updated HEAP version No	Section number changed	Description of and reason for change	, Individual making the change	, Individual making the change

1.9 Roles and responsibilities

This HEAP was written by the senior health economist (TS), who is a co-applicant on the grant. TS has inputted into the design of the wider trial as well as taken the lead on designing the economic evaluation component. TS will be analysing and writing up the economic evaluation. The junior health economist (EM) will check analyses and review the write-up for accuracy. EM has also reviewed and commented on the HEAP.

1.10 Signature(s):

The following people have reviewed the Health Economic Analysis Plan and are in agreement with its contents			
Name	**Role**	**Signature**	**Date**
Tracey Sach	Lead Health Economist		
Prof Alan Montgomery	Trial Statistician		
Prof Kim Thomas	Chief Investigator		

1.11 Abbreviations/glossary of terms/definitions

List any abbreviations and/or acronyms used within the HEAP alongside their meanings/definitions

Abbreviation	Meaning
CEA	Cost Effectiveness Analysis
CEAC	Cost Effectiveness Acceptability Curve
CHU-9D	Child Health Utility - Nine Dimensions
CUA	Cost Utility Analysis
EQ-5D-5L	EuroQol Five Dimensions Five Levels
ICER	Incremental Cost Effectiveness Ratio
NB-UVB	Narrowband Ultraviolet B
NHS	National Health Service
QALY	Quality-Adjusted Life Year

SECTION 2: TRIAL INTRODUCTION AND BACKGROUND

2.1 Trial background and rationale

Vitiligo is a pigmentary disorder of the skin, characterised by the appearance of pale white patches. The condition is associated with multiple other autoimmune conditions such as thyroid disease, alopecia areata and inflammatory bowel disease (Gill, L., 2016). The aetiology of vitiligo is largely unknown (Alikhan, A., 2011), and as such there is currently no cure for the disease. Whilst treatments do exist (Anbar, T.S., 2014), for many, their efficacy has not been rigorously tested. These uncertainties were acknowledged in the James Lind Alliance top ten research priority areas for vitiligo research, with two of these focusing on the use of light therapy and its effectiveness when combined with creams or ointments (Eleftheriadou, V., 2011).

As such, the HI-Light trial will evaluate the use of a home-based, self-administered NB-UVB (narrowband ultra violet-B) light therapy both with and without topical corticosteroids, in comparison to the application of topical corticosteroids alone in vitiligo patients.

2.2 Aim(s) of the trial:

The HI-LIGHT trial aims to estimate the comparative effectiveness of topical corticosteroids (mometasone furoate 0.1% ointment) versus (i) home-based NB-UVB light, and (ii) the combination of topical corticosteroids and home-based NB-UVB light therapy for the management of early and limited vitiligo in adults and children.

2.3 Objectives and/or research hypotheses of the trial

The Primary objective of the trial is to evaluate the comparative safety and effectiveness of home-based interventions (potent topical corticosteroids and hand-held NB-UVB light) for the management of early and limited vitiligo in adults and children. Specifically, comparing:

a. Potent topical corticosteroid (mometasone furoate 0.1% ointment) with hand-held NB-UVB light;

b. Potent topical corticosteroid (mometasone furoate 0.1% ointment) with combination of handheld NB-UVB light and potent topical corticosteroid.

The secondary objectives are:

i) To assess whether treatment response (if any) is maintained once the intervention is stopped.
ii) To compare the cost-effectiveness of the interventions from a National Health Service (NHS) and a family perspective.

2.4 Trial population

Inclusion criteria: Patients 5 years of age or over with a diagnosis of non-segmental vitiligo confirmed by a dermatologist; Vitiligo limited to approximately 10% or less of body surface area (assessed prerandomisation), with at least one patch that is reported by the participant to have been active in the last 12 months; No other active therapy for vitiligo (or willing to stop current treatment – no washout period required); Able to administer the intervention safely at home (with parental/guardian help for small children or those wishing to treat a patch not accessible for self-treatment); Able and willing to give informed consent (or parental/guardian consent in the case of children (under 16s)).

Other concomitant treatments and medications, with the exception of those listed under 'Exclusion criteria' are acceptable.

Exclusion criteria: Other types of vitiligo (e.g. segmental or universal vitiligo); Patients with vitiligo limited to areas of the body for which NB-UVB light therapy or potent topical corticosteroids would be inappropriate (e.g. around the genitals); History of skin cancer (ever); History of radiotherapy use (ever); Photosensitivity (e.g. lupus, polymorphic light eruption, solar urticaria, chronic actinic dermatitis, actinic prurigo, porphyria or other photosensitivity disorders (eg. dermatomyositis)); Pregnant, breastfeeding or likely to become pregnant during the 9-month treatment period; Current use of immunosuppressive drugs (e.g. ciclosporin, azathioprine, mycophenolate mofetil, methotrexate, systemic tacrolimus); Allergy or any contraindication to mometasone furoate or any of its components (e.g any cutaneous bacterial, viral or fungal infections in the area to be exposed to trial treatments); Current participation in another clinical trial or intervention study; Marked evidence of Koebner phenomenon.

Only one participant will be recruited per family. If more than one person is eligible for entry into the trial, the choice of who should take part will be made by the family members themselves. This decision has been made to prevent accidental confusion of blinded trial treatments for people living in the same household.

2.5 Intervention and comparator(s)

Once enrolled in the trial, participants will select up to three patches of vitiligo to be treated, one in each of the following anatomical regions: head and neck, hands and feet, and rest of the body. Of these, one patch will be defined as the primary target patch that the participant would most like to see a response in. There will be 3 comparison treatment arms:

1) NB-UVB plus topical corticosteroid

2) NB-UVB plus placebo topical corticosteroid

3) Topical corticosteroid plus dummy NB-UVB device

Notably, topical corticosteroids are currently considered standard care for those seeking treatment for their vitiligo. All treatment arms will be self-administered at home, for a 9-month period following a pre-defined treatment schedule. All participants will receive training, prior to randomisation, in how to correctly use the light therapy device.

2.6 Trial design

The trial is a multi-centre 3-arm, double-blinded, randomised controlled trial recruiting both adults and children (5 years and older) with early and limited vitiligo.

The revised target sample size of this trial is 516 participants. Participants will be randomly allocated to each of the 3 study arms in a 1:1:1 ratio, and will undergo a 9 month treatment phase, followed by a 12 month follow-up phase which includes 3-monthly questionnaires.

The primary outcome measure is the noticeability of the vitiligo as reported by the participant at 9 months, using the Vitiligo Noticeability Scale (VNS) (Batchelor, J.M., 2016) compared to baseline (a digital image of the vitiligo patch taken at baseline will facilitate comparison).

Secondary outcome measures include: onset of treatment response, participant-reported treatment success, percentage repigmentation, quality of life (assessed at baseline, 9 months, 21 months), time burden of treatment, maintenance of treatment response, and cost-effectiveness.

Full details of the trial can be found in the published protocol (Haines et al 2018).

2.7 Trial start and end dates

Trial recruitment started in May 2015 and finished in June 2017. The follow up period will until December 2018, meaning x/x patients will not complete the health economic questions at 18 and 21 months.

SECTION 3: ECONOMIC APPROACH/OVERVIEW

3.1 Aim(s) of economic evaluation

The aim of this economic evaluation is to determine the cost-effectiveness, from an NHS perspective, of i) active hand-held NB-UVB light compared to standard care (topical corticosteroids only) and ii) active hand-held NB-UVB with topical corticosteroids compared to standard care (topical corticosteroids only), in the treatment of vitiligo in adults and separately in children (aged 5 to 10 years old) and young people (aged 11 to 17 years).

3.2 Objectives(s)/hypotheses of economic evaluation

The primary objective of the health economic evaluation is to estimate the cost-effectiveness of i) active hand-held NB-UVB light compared to standard care (topical corticosteroids only) and ii) active hand-held NB-UVB with topical corticosteroids compared to standard care (topical corticosteroids only) in the treatment of vitiligo in adults and separately in children using individual level data collected within a trial. A secondary objective is to see if estimated cost-effectiveness differs in young people (aged 11-17 years old) depending on which utility instruments is used to estimate the quality of life aspect of Quality-adjusted Life years (QALYs).

3.3 Overview of economic analysis

Brief outline of the type of economic evaluation to be undertaken, outlining the analysis plan and the methods that will be used

e.g. The within-trial economic analysis will be performed using individual patient level data from the [name] trial. The analytical approaches will take the form of cost-effectiveness and cost-utility analysis. Based on trial evidence, incremental cost-effectiveness (and cost-utility) ratios will be calculated by taking a ratio of the difference in the mean costs and mean effects (or utility measure).

The within-trial economic analysis (21 month time frame) will use individual participant level data from the HI-LIGHT trial. The base case analysis will undertake a cost-utility analysis from an NHS perspective for adults and separately children and young people. A secondary analysis will consider the cost effectiveness using the primary outcome measure. It is expected that the majority of costs and benefits will be captured in this period, and therefore it is not considered necessary to develop a decision-analytic model.

The evaluation will adhere to published guidelines for the economic evaluation of health care interventions as appropriate (Drummond et al 2015; Ramsey et al 2015; Glick et al 2014; Husereau, D., 2013).

3.4 Jurisdiction

The trial is being conducted in the UK which has a national health service (NHS), providing publicly funded healthcare which is largely free of charge at the point of use.

3.5 Perspective(s)

Primarily, the analysis will take an NHS perspective in keeping with the NICE reference case (NICE 2013). Presented separately will be the out of pocket costs incurred by participants and where applicable their parents/guardians, reflecting a personal perspective. The time

spent by patients administering the light therapy will be estimated and costed but presented in the wider perspective only as this is not a cost to the NHS.

3.6 Time horizon

The primary economic analysis will compare the costs and consequences over the 21 months follow-up period from randomisation.

SECTION 4: ECONOMIC DATA COLLECTION AND MANAGEMENT

4.1 Statistical software used for HE analysis

Stata SE version 14 will be used for exploratory analysis and main statistical analysis.

4.2 Identification of resources

In keeping with the chosen perspective the base case will capture the intervention costs to the NHS and the participant's wider use of the NHS (including health care visits and prescriptions). Participants personal out of pocket expenses incurred as a result of vitiligo and their time costs undertaking light therapy will be captured in a separate analysis taking a broader perspective.

4.3 Measurement of resource use data

Resource use for the treatment phase will be collected at 9 months, using information recorded by participants in daily diaries and in case report forms. In the follow-up period, resource use will be collected via participant questionnaires at 12, 15, 18 and 21 months.

4.4 Valuation of resource use data

The cost of the intervention will be estimated at the individual level.

NB-UVB Device:

In costing the intervention, the cost of the hand held device, personal protective equipment (such as googles and gloves) and any replacement devices required due to malfunction or damage will be calculated in discussion with a medical physicist and the trial team. During the trial, if participants report a faulty device, a replacement device will be issued instead of repairing the existing device. The number of devices received per participant over the course of the trial will be recorded. Participants will also receive training in how to use the device correctly, through practical demonstration, written instructions and a video. The time spent by nurses delivering this training will be captured in the CRF and costed appropriately.

As these devices are not routinely prescribed, there are several unknowns about how they would be rolled out within the NHS if they were to be adopted. In example of this, it is not clear how they would be distributed directly to patients, the level of routine maintenance the devices would require, as well as the level of training participant's would be provided with when they were first issued the device. All of these areas will be considered and where any assumptions are made, these will be explicitly stated.

Topical Corticosteroid:

Participants receiving the topical corticosteroid intervention will be supplied with two, 90g, tubes of ointment. The cost of the topical corticosteroid: mometasone furoate 0.1%, will be sourced from the Prescription Cost Analysis (Health and Social Care Information Centre, 2017).

It is possible that participants will request additional ointment, and instances of this will be recorded and costed appropriately.

Side effects requiring medical attention from either the NV-UVB device or topical corticosteroid ought to be picked up in the self-report questionnaires completed by participants and thus to avoid double counting data collected on adverse events in the CRF will not also be costed.

Unit Costs:

All resource use relevant to the NHS perspective will be valued using UK unit costs (in £Sterling) from the most current price year available at the time of the analysis. Unit costs will be identified from published sources, such as Unit Costs of Health and Social Care (PSSRU, 2017), Prescription Cost Analysis (Health and Social Care Information Centre, 2017) and NHS Reference Costs (Department of Health, 2017). Where it is not possible to find a nationally published unit cost, it may be necessary to source a unit cost locally. A table of unit costs, together with their sources will be produced.

Personal costs incurred by participants as out of pockets costs due to their vitiligo, will be valued using patient reported estimates. The time costs for adult participants, along with the parents of child participants, for applying the interventions will be valued using the human capital approach, which assumes that a person's productivity is equal to their wage rate. It will be assumed that parents of child participants have supervised their children using the interventions if a second pair of goggles (for the parent) have been requested.

As participants are not being asked about their personal earnings, an average gross hourly rate will be assumed, based on the rates reported in the Annual Survey of Hours and Earnings (ASHE) (ONS, 2017). Importantly, a cost will not be attached to the time spent using the interventions for child participants, this will be reported in hours and minutes only.

Total Costs:

The cost of all reported resource use (relevant to an NHS perspective) will be calculated for each participant. These figures will then be summed for each participant, giving a total cost over the 21 month period. For each of the different treatment arms, a mean cost per participant will be calculated.

4.5 Identification of outcome(s)

Quality of Life:

The primary economic outcome measure will be Quality Adjusted Life Years (QALYs) estimated using utility scores obtained using the EQ-5D-5L instrument for the analysis focused on adults (aged 18 years and over) and the CHU-9D in the analysis focussed on children and young people (aged under 18 years). For participants aged 5-6 years old, the CHU-9D will be completed by parental proxy, but for all other ages these measures will be self-completed.

Vitiligo Noticeability Scale:

The primary clinical outcome measure in the HI-LIGHT trial is participant reported treatment success, measured at 9 months. Treatment success, a binary outcome, is defined by whether the participant responds that their target vitiligo patch is “a lot less noticeable” or “no longer noticeable” in response to the question: "Compared to the start of the study, how noticeable is the vitiligo now?" (from the Vitiligo Noticeability Scale).

4.6 Measurement of outcome(s)

Utility measurements will be collected in person at clinic visits at baseline and 9 months and via postal/online questionnaire at 21 months.

4.7 Valuation of outcome(s)

In the cost utility analysis, the responses received on the quality of life instruments will be converted to utility scores using UK preference weights in line with current recommendations at the time of the analysis (NICE 2017; Devlin et al 2016). Following this, the utility values will be used to calculate the number of quality adjusted life years (QALYs) generated over the trial period of 21 months, using both linear interpolation and area under the curve analysis with and without baseline adjustment (Manca, 2005). Separate cost-utility analysis will report the incremental cost per QALY based on the EQ-5D-5L responses (for participants aged 18 years and over) and the CHU-9D responses (for participants aged 5-17) from an NHS perspective.

SECTION 5: ECONOMIC DATA ANALYSIS

5.1 Analysis population

The economic base-case analysis will take an intention to treat principle approach including all randomised participants.

5.2 Timing of analyses

The final analysis will be a within-trial analysis, taking a 21 month time horizon.

5.3 Discount rates for costs and benefits

As the time horizon being evaluated is 21 months, costs and benefits in months 13 to 21 will be discounted using recommended rates as appropriate (NICE, 2013).

5.4 Cost-effectiveness threshold(s)

Detail the cost-effectiveness threshold(s) to be used in the analysis/interpretation

e.g. The estimated mean QALYs and costs associated with each treatment option will be combined with a feasible range of values for decision makers' willingness to pay (ʎ), to obtain distribution of net benefits at different levels of ʎ. The primary economic analysis will use a cost-effectiveness threshold of £20,000 per QALY.

5.5 Statistical decision rule(s)

As appropriate, all statistical tests will be two-sided with the statistical significance level set at 5%.

5.6 Analysis of resource Use

Mean (sd) resource use per participant will be estimated for each randomised group. Mean difference (95% CI) in mean resource use between arms (NB-UVB alone to TCS alone; and NB-UVB plus TCS compared with TCS alone) will be presented.

5.7 Analysis of costs

Mean (sd) cost per participant will be estimated for each randomised group. Mean difference (95% CI) in mean cost between arms (NB-UVB alone to TCS alone; and NB-UVB plus TCS compared with TCS alone) will be estimated unadjusted.

5.8 Analysis of outcomes

The primary outcome for the economic evaluation will be quality-adjusted life years (QALYs) of participants over 21 months. Mean (SD) utility and mean (sd) QALYS per participant per randomised group will be presented and mean difference (95% CI) in utility and QALYs between arms (NB-UVB alone to TCS alone; and NB-UVB plus TCS compared with TCS alone) will be estimated unadjusted.

5.9 Data cleaning for analysis

Before carrying out analyses, plausibility checks will be performed on the relevant data fields, such as resource use and reported outcome measures, such as quality of life. Where problems are identified, the health economist will contact the data manager of the trial for clarification.

5.10 Missing data

Trial data will be examined for any missing data, in particular the amount of missing data and the likely mechanism of missingness. Based on this an appropriate method for dealing with missing data will be determined. If missing at random seems a reasonable assumption, multiple imputation will be undertaken (Faria et al 2004). However, if there is uncertainty about the mechanism of missingness, i.e. it might be missing not at random, another methods such as pattern-mixture models will be used (Leurant et al 2018). Comparing different approaches will enable us to assess the impact the underlying assumption about missingness has on results. Since it is known in advance that around 50 participants will not have data at 21 months and or 18 months due to follow-up being stopped early to lock the database to enable sufficient analysis time, it is important to undertake such sensitivity analysis.

5.11 Analysis of cost-effectiveness

If no clinical benefit is found for either NB-UVB alone or NB-UVB plus TCS over TCS alone in the clinical trial then costs and outcomes will not be combined in an economic evaluation. Instead 5.7 and 5.8 will be presented for the benefit of future researchers working in this area whom may wish to develop an economic model for vitiligo.

If a clinical benefit is found for either NB-UVB alone or NB-UVB plus TCS over TCS alone in the clinical trial then Cost and QALY data will be combined to estimate an incremental cost-effectiveness ratio (ICER) and net monetary benefit (NMB) from the NHS perspective comparing NB-UVB alone to TCS alone and separately NB-UVB plus TCS compared with TCS alone. A regression-based approach (such as seemingly unrelated regression equations if appropriate) (Willan et al 2004) will be used.

The primary clinical outcome measure of the HI-Light trial, as described above, will be used in the cost-effectiveness analysis. The number of successful treatments per treatment arm will be totalled and divided by the number treated in the respective arm. A generalised linear model (GLM) for binary outcome will be fitted and presented as unadjusted and adjusted by centre, site of vitiligo and age. If appropriate, having considered dominance and extended dominance, the incremental cost per successful treatment will be calculated.

5.12 Sampling uncertainty

It is likely that costs and outcomes will be skewed, therefore non-parametric bootstrapping will be used to determine the level of sampling uncertainty surrounding the mean ICERs by generating 10,000 estimate of incremental costs and benefits. These estimates will be plotted on a cost-effectiveness plane. In addition, Cost-Effectiveness Acceptability Curves will be produced, which will show the probability that each of the treatment arms is cost effective at different values of willingness to pay.

5.13 Subgroup analysis/Analysis of heterogeneity

Due to different utility instruments being necessary in the different age groups in the study the base case analysis will present two separate cost utility analyses one for adults aged 18 years and over using the EQ-5D-5L and one for children and young people aged 5 years to 17 years using the CHU-9D.

5.14 Sensitivity analyses

A number of sensitivity analyses will be undertaken to explore key uncertainties around important parameters in the economic evaluation.

1. The impact of missing data will be explored by comparing results where multiple imputation is used assuming Missing at random to a pattern-mixture model assuming Missing not at random (Leurent et al, 2018) and a complete case analysis if more than 10% of data is missing.

2. To explore the impact of the different utility instruments being used we have collected both the EQ-5D-5L and the CHU-9D in those participants aged 11 to 17 years. We will estimate QALYs for this age group based on each instrument in order to assess whether they are significantly different such that it could change the conclusion reached.

3. The cost of the NB-UVB device is likely to be a significant cost driver in the analysis. As such, we will examine the uncertainty surrounding the assumptions made in the base case analysis, for example by changing training requirements, the cost of maintenance and so on, based on the uncertainty identified in the device costing process. This will reflect the uncertainty of how the device would be prescribed and used, if it were to be adopted by the NHS.

4. Wider cost perspective – including the costs (if any) incurred by participants and their families in terms of out of pocket costs.

5. Per protocol analysis – (how is compliance being defined in the statistical analysis? – if compliance high then this sensitivity analysis is not needed. Would also only be applicable if the statistical analysis demonstrated evidence of effectiveness.)

6. Cost effectiveness at the 9 months primary outcome follow-up point. Whilst decision makers are usually most interested in longer term cost-effectiveness there may be some justification for repeating the analysis at the primary outcome point (9 months) in case effectiveness is not maintained post-treatment.

SECTION 6: MODELLING AND VALUE OF INFORMATION ANALYSES

6.1 Extrapolation or Decision analytic modelling

The within-trial base case time horizon will be 21 months. It is expected that the majority of costs and benefits will be captured in this period, and therefore it is not considered necessary to develop a decision-analytic model.

6.2 Model type

N/A

6.3 Model structure

N/A

6.4 Treatment effect beyond the end of the trial

N/A

6.5 Other key assumptions

N/A

6.6 Methods for identifying and estimating parameters

N/A

6.7 Model uncertainty

N/A

6.8 Model validation
N/A

6.9 Subgroup analyses/Heterogeneity
N/A

SECTION 7: REPORTING/PUBLISHING

7.1 Reporting standards
The CHEERS reporting quality guidelines will be followed when writing up the health economic evaluation.

7.2 Reporting deviations from the HEAP
Any deviations necessary from the HEAP will be described and justified in the main study report (HTA monograph).

SECTION 8: Appendices

Appendix 1: Resource use data collected (including template examples of the resource use data collection sheets and resource use questionnaires)

[To do: insert resource use questionnaire(s)]

Appendix 1: Example Tables

Unit Costs Table (UK£ sterling, Price Year)

Cost Item	Unit Cost (£)	Source
Intervention		
NB-UVB Device		
Topical Corticosteroid		
Primary Care		
GP		
Practice Nurse		
Pharmacist*		

Hospital Doctor		
Hospital Nurse		
Therapist (assume psychologist)		
Light therapy appointment		
Other		
Medication		

*Note assumed to be a community pharmacist

Mean (Standard Deviation) resource use according to treatment arm over 9 month treatment phase

	NB-UVB + TCS (n=)		**TCS + Placebo NB-UVB (n=)**		**NB-UVB + Placebo TCS (n=)**	
	Mean	**Std dev**	**Mean**	**Std dev**	**Mean**	**Std dev**
Intervention						
NB-UVB Device						
Topical Corticosteroid						
Primary Care and Community						
GP						
Practice Nurse						
Pharmacist						
Secondary Care						
Hospital Doctor						
Hospital Nurse						
Therapist						
Light therapy appointment						
Other						
Medication						

Mean (Standard Deviation) costs according to treatment arm over 9 month treatment phase (UK£Sterling, Price Year)

	NB-UVB + TCS (n=)		**TCS + Placebo NB-UVB (n=)**		**NB-UVB + Placebo TCS (n=)**	
	Mean	**Std dev**	**Mean**	**Std dev**	**Mean**	**Std dev**

Intervention						
NB-UVB Device						
Topical Corticosteroid						
Primary Care and Community						
GP						
Practice Nurse						
Pharmacist						
Secondary Care						
Hospital Doctor						
Hospital Nurse						
Therapist						
Light therapy appointment						
Other						
Medication						

Mean (Standard Deviation) resource use according to treatment arm over months 10 to 21 follow-up phase

	NB-UVB + TCS (n=)		**TCS + Placebo NB-UVB (n=)**		**NB-UVB + Placebo TCS (n=)**	
	Mean	**Std dev**	**Mean**	**Std dev**	**Mean**	**Std dev**
Intervention						
NB-UVB Device						
Topical Corticosteroid						
Primary Care and Community						
GP						
Practice Nurse						
Pharmacist						
Secondary Care						
Hospital Doctor						
Hospital Nurse						

Therapist						
Light therapy appointment						
Other						
Medication						

Mean (Standard Deviation) costs according to treatment arm over months 10 to 21 follow-up phase (UK£Sterling, Price Year)

	NB-UVB + TCS (n=)		**TCS + Placebo NB-UVB (n=)**		**NB-UVB + Placebo TCS (n=)**	
	Mean	**Std dev**	**Mean**	**Std dev**	**Mean**	**Std dev**
Intervention						
NB-UVB Device						
Topical Corticosteroid						
Primary Care and Community						
GP						
Practice Nurse						
Pharmacist						
Secondary Care						
Hospital Doctor						
Hospital Nurse						
Therapist						
Light therapy appointment						
Other						
Medication						

Mean (Standard Deviation) resource use according to treatment arm over the total 21 months

	NB-UVB + TCS (n=)		**TCS + Placebo NB-UVB (n=)**		**NB-UVB + Placebo TCS (n=)**	
	Mean	**Std dev**	**Mean**	**Std dev**	**Mean**	**Std dev**
Intervention						
NB-UVB Device						
Topical Corticosteroid						
Primary Care and Community						
GP						
Practice Nurse						
Pharmacist						
Secondary Care						
Hospital Doctor						
Hospital Nurse						
Therapist						
Light therapy appointment						
Other						
Medication						

Mean (Standard Deviation) costs according to treatment arm over the total 21 months (UK£Sterling, Price Year)

	NB-UVB + TCS (n=)		**TCS + Placebo NB-UVB (n=)**		**NB-UVB + Placebo TCS (n=)**	
	Mean	**Std dev**	**Mean**	**Std dev**	**Mean**	**Std dev**
Intervention						
NB-UVB Device						
Topical Corticosteroid						
Primary Care and Community						
GP						
Practice Nurse						

Pharmacist						
Secondary Care						
Hospital Doctor						
Hospital Nurse						
Therapist						
Light therapy appointment						
Other						
Medication						

Utility and QALYs

	NB-UVB + TCS (n=)		**TCS + Placebo NB-UVB (n=)**		**NB-UVB + Placebo TCS (n=)**	
	Mean	**Std dev**	**Mean**	**Std dev**	**Mean**	**Std dev**
Adult population aged 18 years and over (n=)						
EQ-5D-5L Baseline						
EQ-5D-5L 9 months						
EQ-5D-5L 21 months						
QALYs						
Children and Young people (aged 5 to 17 years) (n=)						
CHU-9D Baseline						
CHU-9D 9 months						
CHU-9D 21 months						
QALYs (CHU-9D)						
Young people (aged 11 to 17 years) (n=)						
CHU-9D Baseline						
CHU-9D 9 months						
CHU-9D 21 months						
QALYs (CHU-9D)						
EQ-5D-5L Baseline						
EQ-5D-5L						

9 months						
EQ-5D-5L 21 months						
QALYs (EQ-5D-5L)						
Children (aged 5 to 10 years) (n=)						
CHU-9D Baseline						
CHU-9D 9 months						
CHU-9D 21 months						
QALYs (CHU-9D)						

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