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Setting **P**riorities &
Reducing **U**ncertainties for
People with **S**kin **D**isease

Hi-Light trial for the treatment of vitiligo

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Home Intervention of **Light** therapy for the treatment of vitiligo



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Hi-Light trial for vitiligo

- Background
- Aims and objectives
- Methods
- Results
- Conclusions



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Background:

Why home phototherapy?

- Vitiligo Priority Setting Partnership
- Cochrane Systematic review 2010
- New EDF guidelines for vitiligo
- Early treatment more effective?



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Vitiligo PSP



- 1st PSP in Dermatology
- 1600 questions by 461 participants
- Top 10 areas for research identified

Eleftheriadou, V et al Future research into the treatment of vitiligo: where should our priorities lie? Results of the vitiligo priority setting partnership. *BJD* 164: 530–536.



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Top 10 treatment uncertainties for vitiligo

1. How effective are **systemic immunosuppressants** in treating vitiligo?
2. How much do **psychological interventions** help people with vitiligo?
3. Which treatment is more effective for vitiligo: **light therapy or calcineurin inhibitors** (e.g. tacrolimus)?
4. How effective is **UVB light therapy when combined with creams or ointments** in treating vitiligo?
5. What role might **gene therapy** play in the treatment of vitiligo?
6. How effective are **hormones or hormone related substances that stimulate pigment cells** (MSH analogues, afamelanotide) in treating vitiligo?
7. Which treatment is more effective for vitiligo: **calcineurin inhibitors) or steroid creams/ointments**
8. Which treatment is more effective for vitiligo: **steroid creams/ointments or light therapy?**
9. How effective is the **addition of psychological interventions to patients using cosmetic camouflage** for improving their quality of life?
10. How effective is **pseudocatalase cream** (combined with brief exposure to UVB light) in treating vitiligo?



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Cochrane systematic review

- No firm clinical recommendations can be made
- Combination treatments with light seems to be promising



Whitton M, Pinart M, Batchelor *et al.* Interventions for vitiligo. Cochrane Database of Systematic Reviews 2010, Issue 1



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EDF guidelines: SV & limited NSV

- ▶ **First line:** corticosteroids, calcineurin inhibitors
- ▶ **Second line:** Localised NB-UVB therapy
- ▶ **Third line:** surgical techniques if stable



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Early treatment more effective?

- HALLAJI, Z., M. GHIASI, A. EISAZADEH and M. R. DAMAVANDI. Evaluation of the effect of disease duration in generalized vitiligo on its clinical response to narrowband ultraviolet B phototherapy. *Photodermatology Photoimmunology Photomedicine*, 2012, 28(3), 115-9.
- LEE, D. Y., C. R. KIM and J. H. LEE. Recent onset vitiligo on acral areas treated with phototherapy: need of early treatment. *Photodermatology Photoimmunology Photomedicine*, 2010, 26(2), 266-8.
- LEE, D. Y., C. R. KIM, J. H. LEE and J. M. YANG. Recent onset vitiligo treated with systemic corticosteroid and topical tacrolimus: Need for early treatment in vitiligo. *Journal of Dermatology*, 2010, 37(12), 1057-9.



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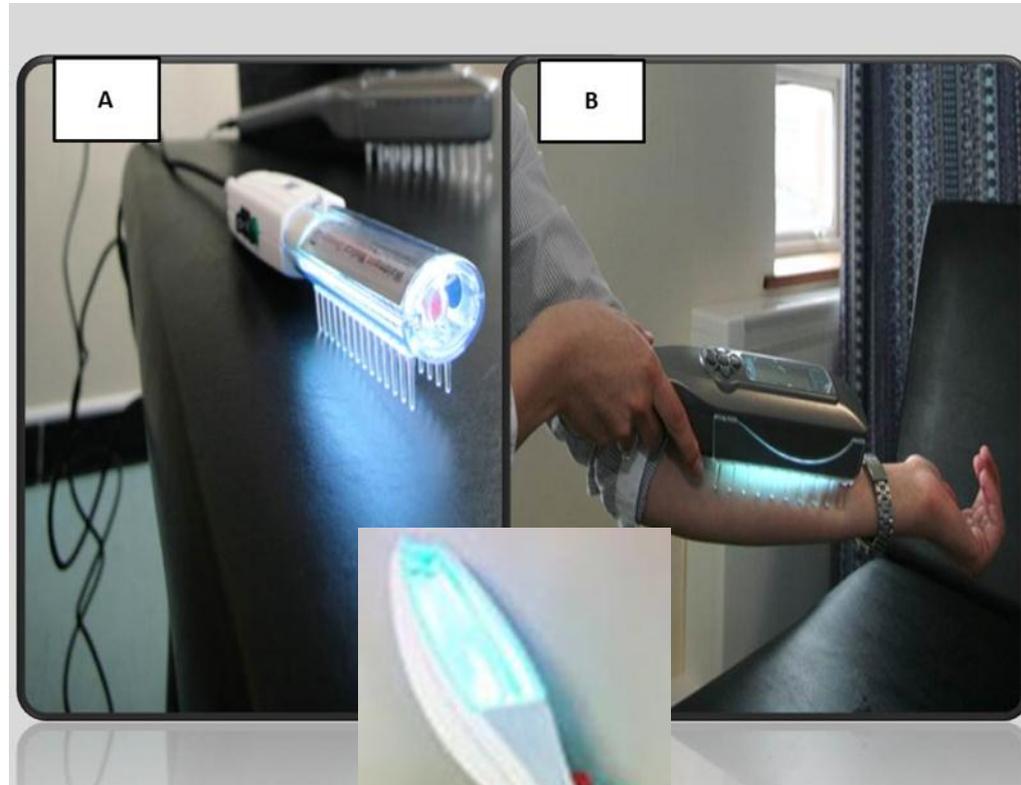
Aims and objectives

- Feasibility of conducting a large RCT:
- Recruitment strategies
 - Educational package on home phototherapy/adherence to treatment
 - Test outcomes for the main trial
 - Output of the devices pre/post trial



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Hand-held phototherapy units



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Home Intervention of **Light** therapy for vitiligo

Multi-centre, pilot, double-blind, placebo controlled trial on hand-held NB-UVB home phototherapy for the treatment of vitiligo



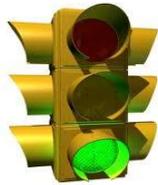
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Methods

- 2 recruitment centres: Nottingham (QMC) and Leicester (LRI)
- + GP practices as Patients Identification Centres
- 3-arm parallel trial: Group A-active Dermfix, Group B-active Waldmann, Group C-placebo Dermfix
- Participants, investigators, independent outcome assessor: blinded
- 4 months treatment duration



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Eligibility



Inclusion criteria

- Vitiligo confirmed by a dermatologist (less than 25% of body surface area)
- Children (aged ≥ 5 years) & adults
- No therapy for vitiligo in the previous 2 weeks and no concurrent treatment during the trial
- Spreading and stable vitiligo
- Able to give informed consent

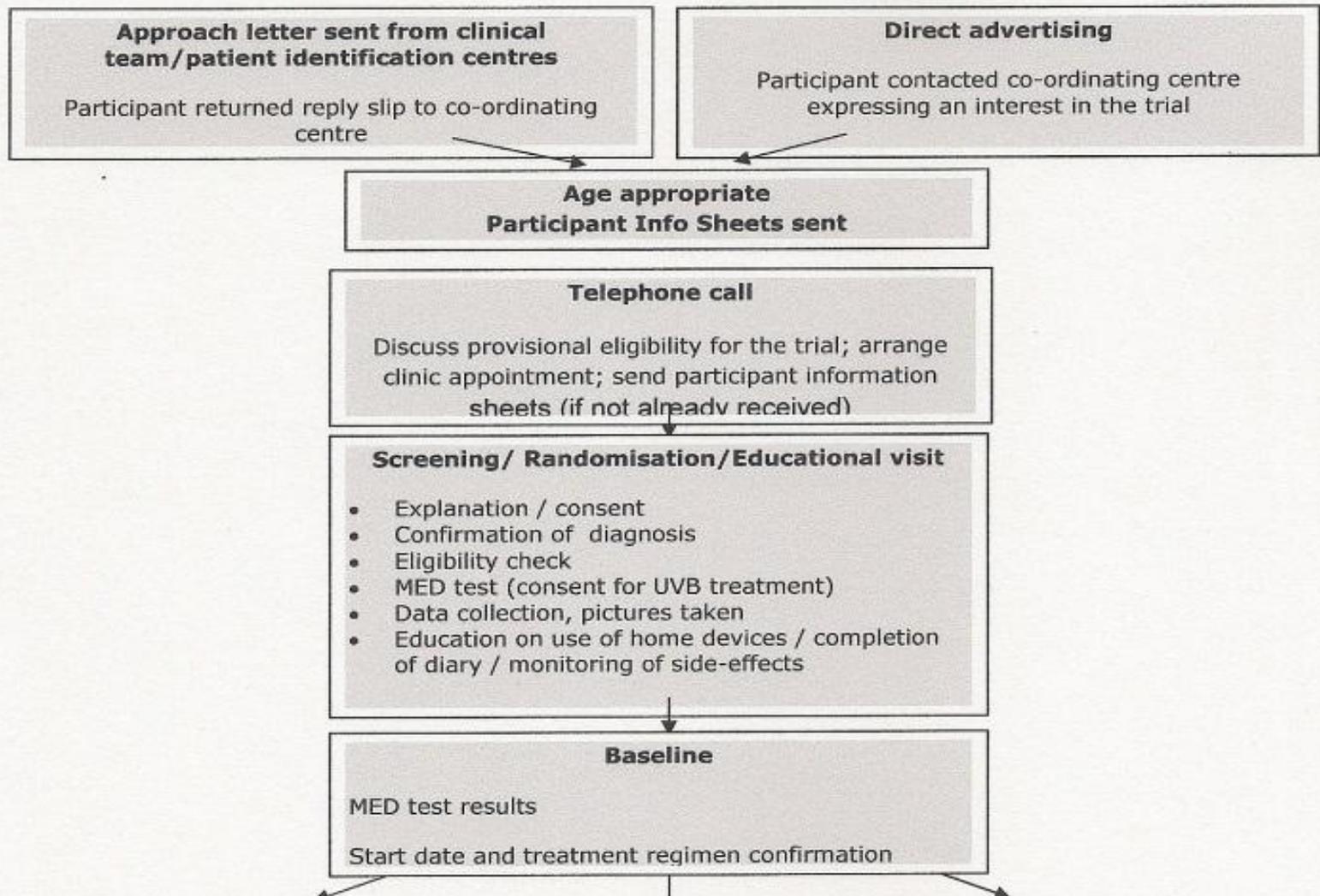
Exclusion criteria

- Segmental vitiligo
- Universal vitiligo
- Previous history of skin cancer
- Recent or concurrent radiotherapy, photosensitivity
- Immunosuppressive or photosensitive drugs
- Pregnant or lactating women
- Major medical co-morbidities
- Vitiligo limited to the genitalia only

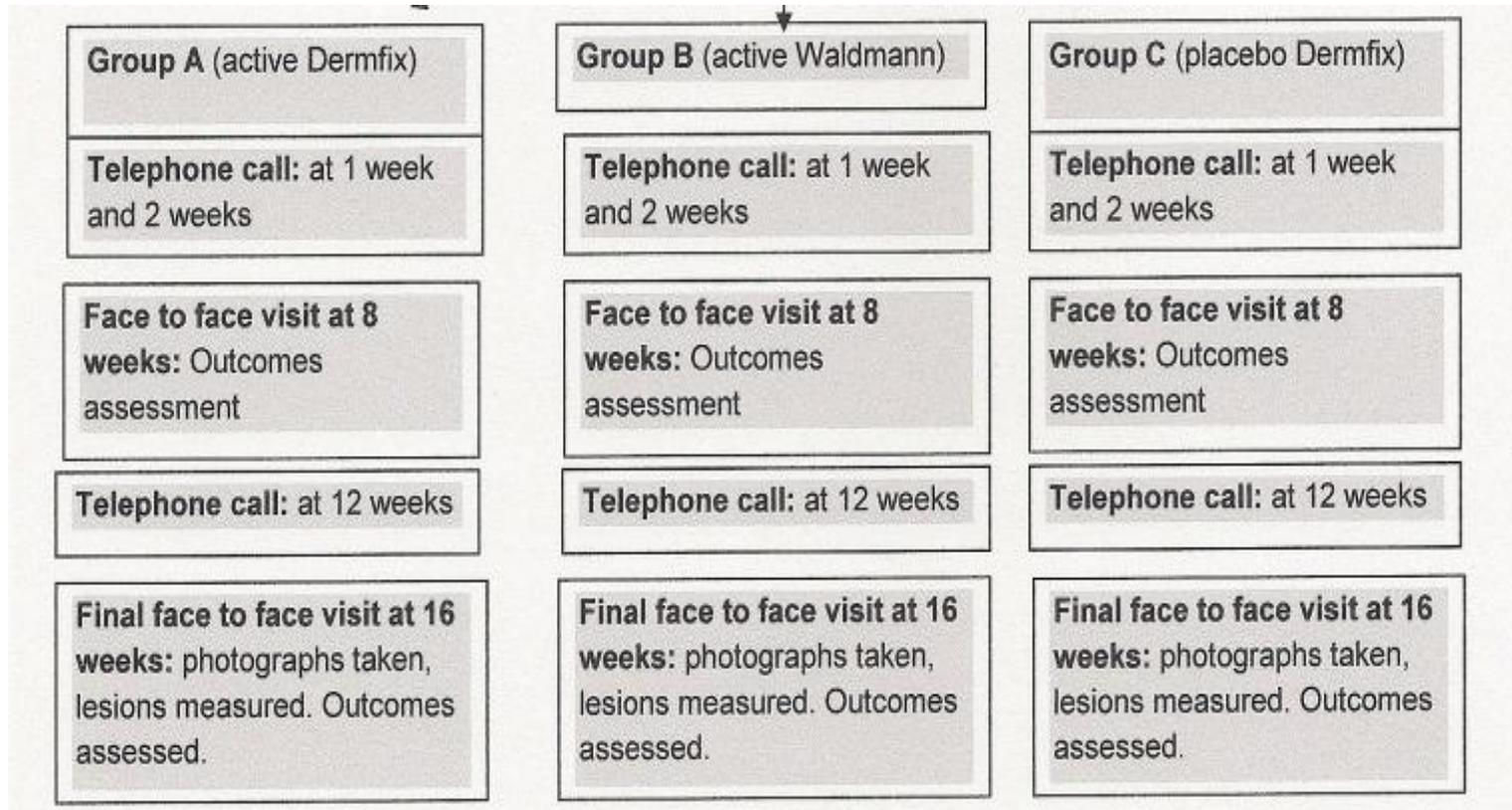


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Trial configuration (1)



Trial configuration (2)



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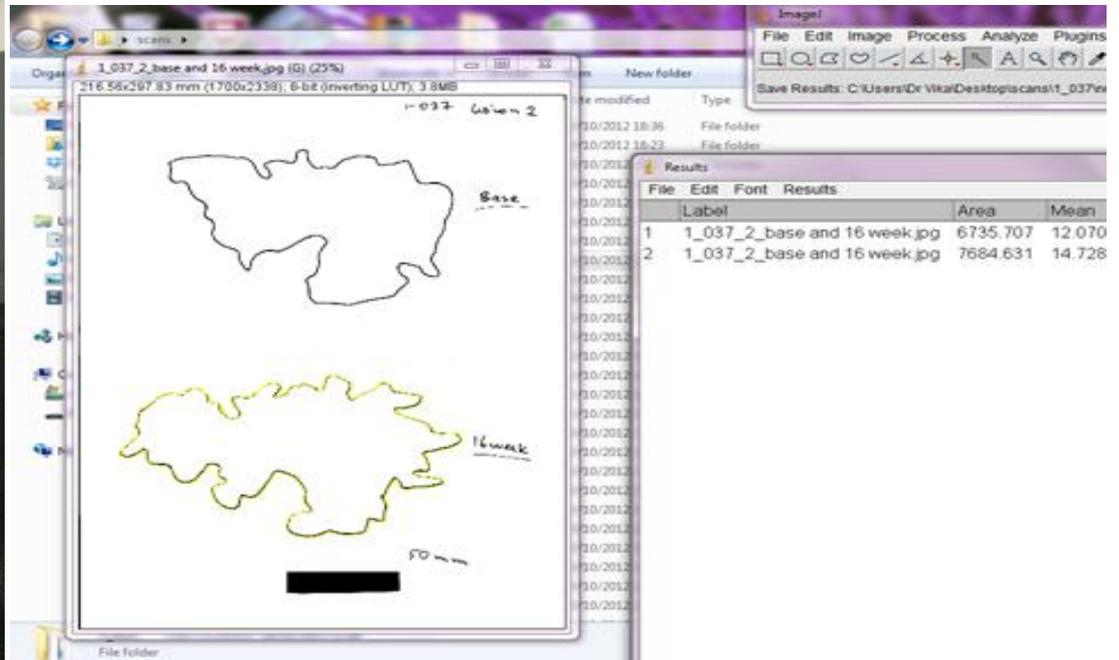
Treatment schedule

Skin Type	Starting time	Exposure time +20% of treatment 1	Exposure time - 20% of treatment 1	Maximum exposure time (MET)	Total duration
I	15 sec	+3 seconds	-3 seconds	3 min	4 months
II	20 sec	+4 seconds	-4 seconds	4 min	4 months
III	25 sec	+5 seconds	-5 seconds	5 min	4 months
IV	30 sec	+6 seconds	-6 seconds	6 min	4 months
V	30 sec	+6 seconds	-6 seconds	6 min	4 months
VI	30 sec	+6 seconds	-6 seconds	6 min	4 months



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Repigmentation measurement



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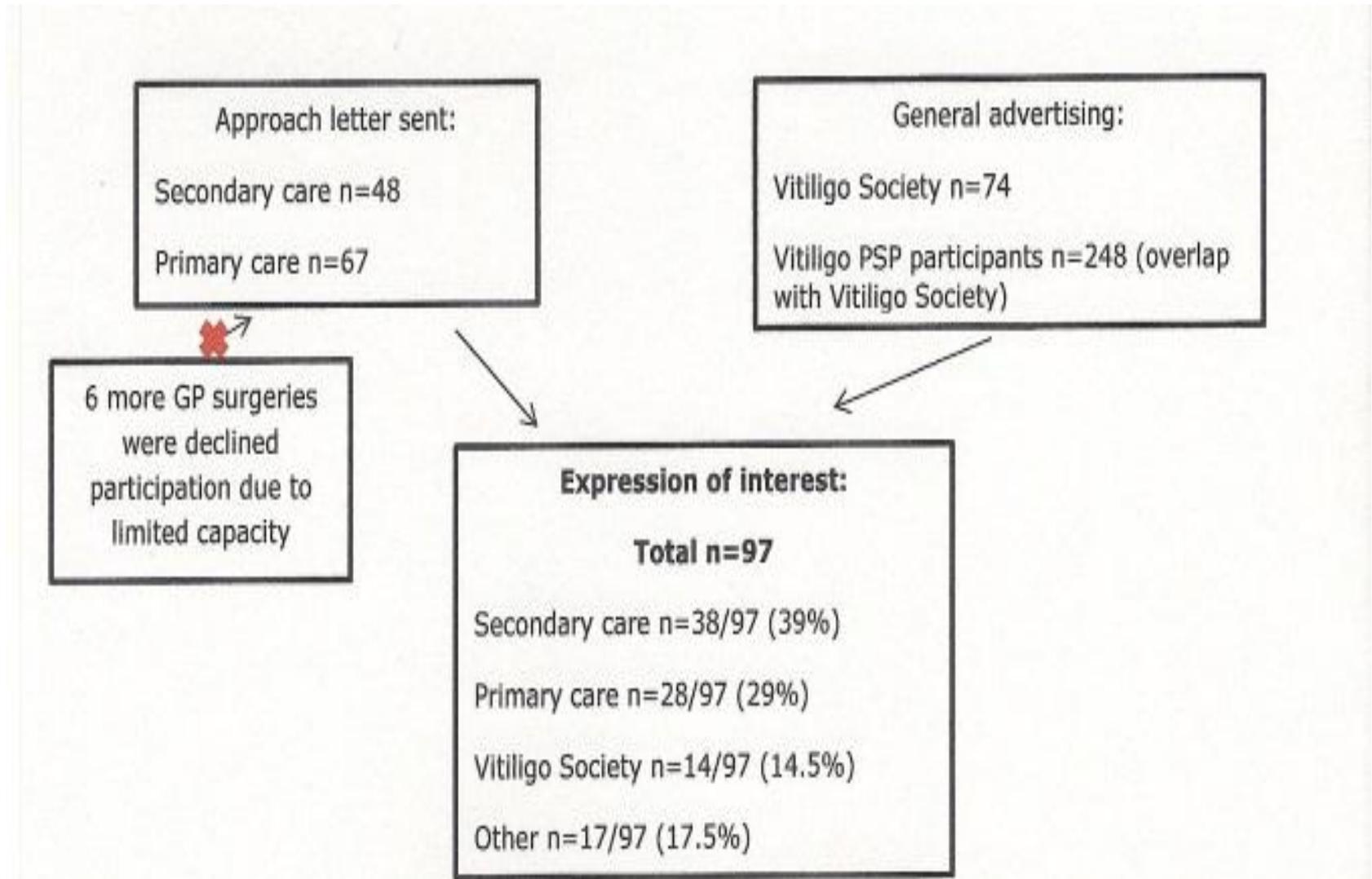
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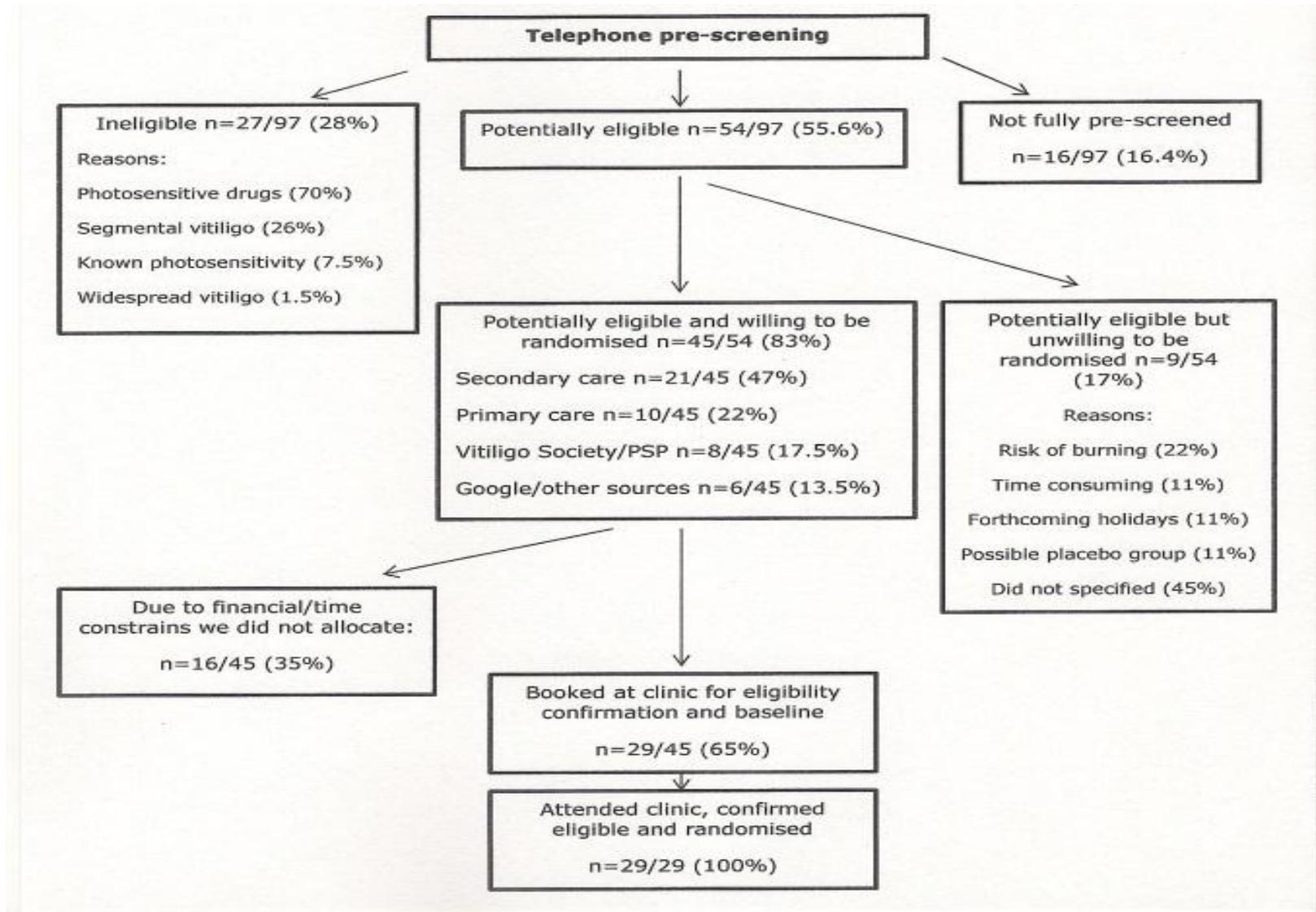


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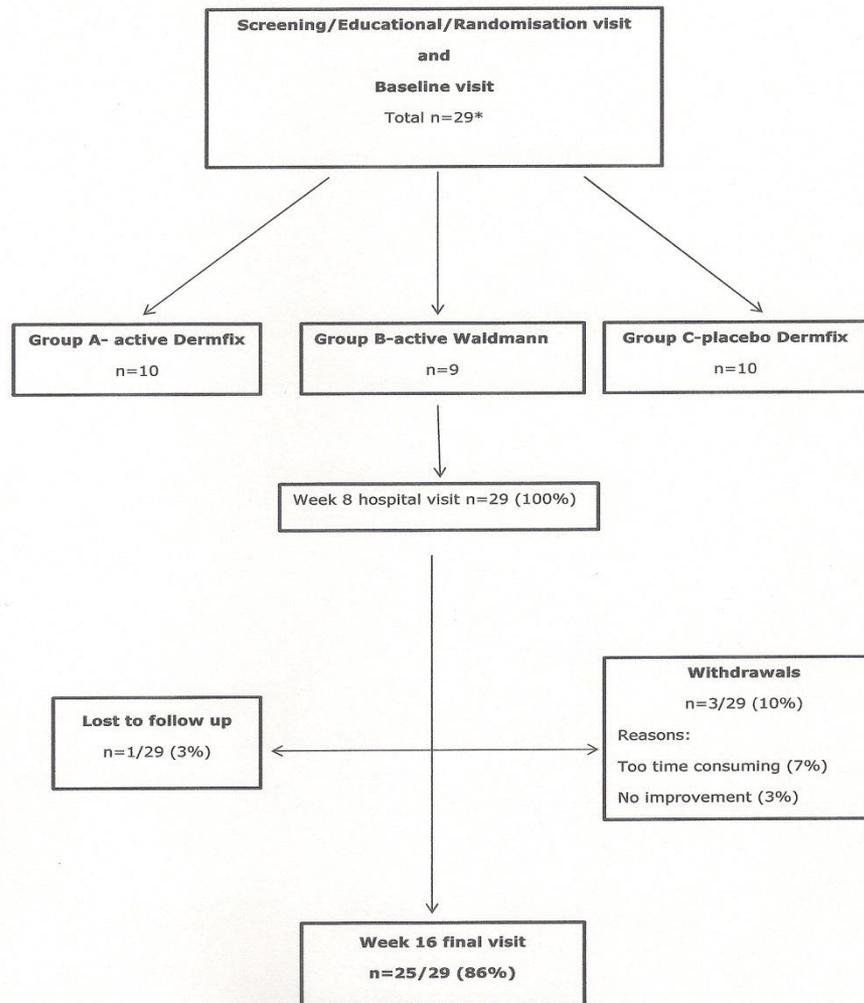
Results (1)



Results (2)



Results (3)



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Adherence

- 28 of 29 diaries retrieved
- 90% (25/29) of patients completed 4 months treatment regimen
- 75% (21/28) performed treatment correctly
- Only 1 episode of grade 3 erythema



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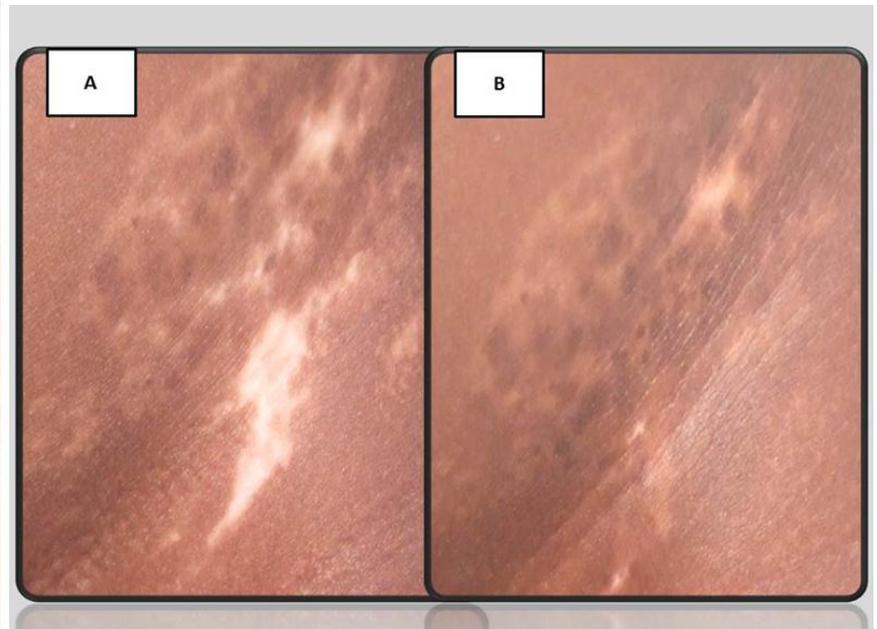
Hand-held devices output pre&post trial

	Dermfix		Waldmann	
	Pre-trial	Post-trial	Pre-trial	Post-trial
Mean output mW/cm²	3.81	3.24	4.5	3.92
SD mW/cm²	0.37	0.42	0.2	0.67
Coefficient of variation	9.7%	12.9%	4.4%	17%
Mean difference	-14.5%		-13%	
Maximum difference pre and post-trial	-28.5%		-38.5%	
Minimum difference pre and post-trial	-7.4%		+10.5%	



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Repigmentation



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Minimal Erythema Dose test

- 45% of patients had different skin type determined by a dermatologist and the MED test



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Conclusions (1)

Recommendations for the main trial:

- Careful choice of transparencies
- Dermfix
- Devices Output pre-trial
- Minimal Erythema Dose
- Educational DVD on hand-held phototherapy



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Conclusions (2)

- Patients/clinicians willing to participate
- Educational package is comprehensive and well tolerated
- National multi-centre RCT on hand-held devices is feasible



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National Institute for Health Research call for a national RCT on vitiligo.....



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Thank you



Trial Management Group:

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Prof. H. Williams

Dr K. Thomas

Dr J. Ravenscroft

Dr J. Batchelor

Mrs Maxine Whitton

Dr R. Dawe

IT specialist: G. Watson

Medical Physicist: R. Farley

Statistician: Samir Mehta

Research nurses:

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Mrs Catherine Shelley

Mrs Jo Llewelyn

Mrs Susan Yule

Co-ordinating centre:

Mrs Lisa Charlesworth

Mrs Jo Perdue

Principle investigators:

Drs J Ravenscroft and A.Alexandroff



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