

# THE LANCET

## Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

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## Supplementary Tables and Figures

**Supplementary Table S1: Change in symptoms from randomisation to four weeks.**

Symptom	Severity at Baseline	OSC + WBRT (N=152)		OSC Alone (N=139)		P-value
		None/mild	Mod/Sev	None/mild	Mod/Sev	
		Severity at 4 weeks		Severity at 4 weeks		
		None/mild	Mod/Sev	None/mild	Mod/Sev	
Sight	None/mild	120 (79%)	10 (7%)	103 (74%)	15 (11%)	0.2227
	Moderate/severe	16 (11%)	5 (3%)	14 (10%)	7 (5%)	
Speech	None/mild	130 (86%)	14 (9%)	120 (86%)	10 (7%)	0.5578
	Moderate/severe	4 (3%)	3 (2%)	7 (5%)	2 (1%)	
Tired	None/mild	59 (39%)	40 (27%)	52 (37%)	35 (25%)	0.6381
	Moderate/severe	15 (10%)	36 (24%)	21 (15%)	31 (22%)	
Drowsiness	None/mild	83 (55%)	49 (27%)	83 (60%)	30 (22%)	0.0151
	Moderate/severe	9 (6%)	18 (12%)	17 (12%)	9 (6%)	
Insomnia	None/mild	88 (58%)	23 (15%)	80 (58%)	16 (12%)	0.5879
	Moderate/severe	24 (16%)	16 (11%)	27 (19%)	16 (12%)	
Confusion	None/mild	126 (83%)	13 (9%)	122 (88%)	9 (6%)	0.6815
	Moderate/severe	10 (7%)	2 (1%)	6 (4%)	2 (1%)	
Memory	None/mild	114 (76%)	16 (11%)	115 (83%)	8 (6%)	0.0860
	Moderate/severe	15 (10%)	5 (3%)	13(9%)	2 (1%)	

Symptom	Severity at Baseline	OSC + WBRT (N=152)		OSC Alone (N=139)		P-value
		Severity at 4 weeks		Severity at 4 weeks		
Mood	None/mild	109 (73%)	15 (10%)	102 (74%)	18 (13%)	0.3385
	Moderate/severe	19 (13%)	6 (4%)	10 (7%)	8 (6%)	
Dizziness	None/mild	124 (83%)	12 (8%)	113 (81%)	7 (5%)	0.7157
	Moderate/severe	7 (5%)	7 (5%)	11 (8%)	8 (6%)	
Seizures	None/mild	147 (98%)	1 (1%)	133 (96%)	4 (3%)	0.1989
	Moderate/severe	2 (1%)	0 (0%)	2 (1%)	0 (0%)	
Weakness	None/mild	86 (57%)	33 (22%)	84 (60%)	21 (15%)	0.3777
	Moderate/severe	14 (9%)	18 (12%)	15 (11%)	19 (14%)	
Headache	None/mild	129 (85%)	7 (5%)	119 (86%)	9 (6%)	0.8350
	Moderate/severe	10 (7%)	5 (3%)	8 (6%)	3 (2%)	
Nausea	None/mild	133 (88%)	14 (9%)	134 (96%)	3 (2%)	0.0067
	Moderate/severe	3 (2%)	1 (1%)	2 (1%)	0 (0%)	
Indigestion	None/mild	134 (90%)	7 (5%)	119 (86%)	7 (5%)	0.4783
	Moderate/severe	7 (5%)	1 (1%)	9 (6%)	4 (3%)	
Hair loss	None/mild	95 (64%)	48 (32%)	133 (97%)	1 (1%)	0.0001

Symptom	Severity at Baseline	OSC + WBRT (N=152)		OSC Alone (N=139)		P-value
		Severity at 4 weeks		Severity at 4 weeks		
	Moderate/severe	3 (2%)	3 (2%)	3 (2%)	0 (0%)	
Weight gain	None/mild	127 (86%)	8 (5%)	118 (86%)	7 (5%)	0.8346
	Moderate/severe	9 (6%)	4 (3%)	7 (5%)	6 (4%)	
Weight loss	None/mild	132 (89%)	6 (4%)	118 (86%)	7 (5%)	1.000
	Moderate/severe	8 (5%)	3 (2%)	12 (9%)	1 (1%)	
Appearance	None/mild	128 (86%)	9 (6%)	121 (87%)	7 (5%)	0.5437
	Moderate/severe	5 (3%)	6 (4%)	7 (5%)	4 (3%)	
Dry/Itchy scalp	None/mild	137 (93%)	10 (7%)	135 (98%)	1 (1%)	0.0057
	Moderate/severe	0 (0%)	1 (1%)	2 (1%)	0 (0%)	
Thrush	None/mild	132 (89%)	8 (5%)	125 (90%)	10 (7%)	1.000
	Moderate/severe	4 (3%)	4 (3%)	2 (1%)	2 (1%)	

**Notes:**

For each symptom, the question posed was “Has the patient experienced any problems in the following areas?”, with possible responses “None”, “Mild”, “Moderate”, or “Severe”.

Patients with data at both baseline and four weeks are summarised. Percentages are calculated from patients with non-missing data.

P-values are from Fisher’s Exact Test, and compare the number of patients reporting moderate or severe symptoms at four weeks.

Example: For hair loss in the OSC+WBRT arm, in total 143/149 (96%) patients had no/mild hair loss problems at baseline, and 98/149 (66%) had no/mild hair loss problems at 4 weeks. In more detail: 95 (64%) patients had no/mild problems at both baseline and 4 weeks; 48 (32%) had no/mild problems at baseline but a moderate/sever problem at 4 weeks; 3 (2%) had a moderate/severe problem at baseline but no/mild problems at 4 weeks; and 3 (2%) had a moderate/severe problem at both baseline and 4 weeks.

**Supplementary Table S2: Dexamethasone dose changes**

During first...	Dexamethasone...		WBRT + OSC N=245	OSC alone N=233	P-value
4 weeks	Stopped	Yes	16 (7%)	11 (5%)	0.4358
		No	229 (93%)	222 (95%)	
	Reduced	Yes	143 (58%)	142 (61%)	0.5771
		No	102 (42%)	91 (39%)	
8 weeks	Stopped	Yes	30 (12%)	24 (10%)	0.5641
		No	215 (88%)	209 (90%)	
	Reduced	Yes	167 (68%)	153 (66%)	0.6268
		No	78 (32%)	80 (34%)	

Note: Dexamethasone is said to have been stopped if the patient spent any time not taking it during the four or eight weeks after randomisation, even if they subsequently started taking it again. Similarly, dexamethasone is said to have been reduced if the patient spent any time receiving a lower dose than that reported at randomisation, even if the dose was subsequently raised again.

Note: Treatment arms are compared using Fisher's Exact Test.

**Supplementary Table S3: Subgroup survival times.**

Subgroup	Value	Statistic	WBRT + OSC	OSC alone
Sex	Male	N	157	157
		Median OS	9.4	7.9
		95% CI	7.0, 11.3	6.6, 8.9
	Female	N	112	112
		Median OS	9.4	8.4
		95% CI	7.1, 11.9	7.6, 10.3
Age Group	<60	N	67	48
		Median OS	10.4	7.6
		95% CI	6.3, 13.4	4.6, 10.1
	60 – 69	N	110	123
		Median OS	11.0	7.9
		95% CI	8.7, 12.6	6.4, 8.4
	70+	N	92	98
		Median OS	7.0	9.3
		95% CI	5.9, 9.4	7.7, 11.4
KPS	<70	N	101	102
		Median OS	5.7	5.7
		95% CI	5.0, 7.0	4.4, 7.3

Subgroup	Value	Statistic	WBRT + OSC	OSC alone
	70+	N	168	167
		Median OS	12.1	9.7
		95% CI	10.4, 13.4	8.3, 11.4
Extra-cranial metastases	No	N	122	124
		Median OS	10.4	8.4
		95% CI	7.9, 12.1	7.7, 9.7
	Yes	N	147	145
		Median OS	8.4	7.6
		95% CI	6.7, 10.3	6.4, 8.9
Primary NSCLC	Controlled	N	98	94
		Median OS	12.1	8.3
		95% CI	10.4, 15.1	7.6, 11.4
	Uncontrolled	N	169	172
		Median OS	7.7	7.7
		95% CI	6.4, 9.3	6.7, 8.4
Number of brain metastases	1	N	80	82
		Median OS	8.9	8.3
		95% CI	7.0, 11.9	6.9, 9.9



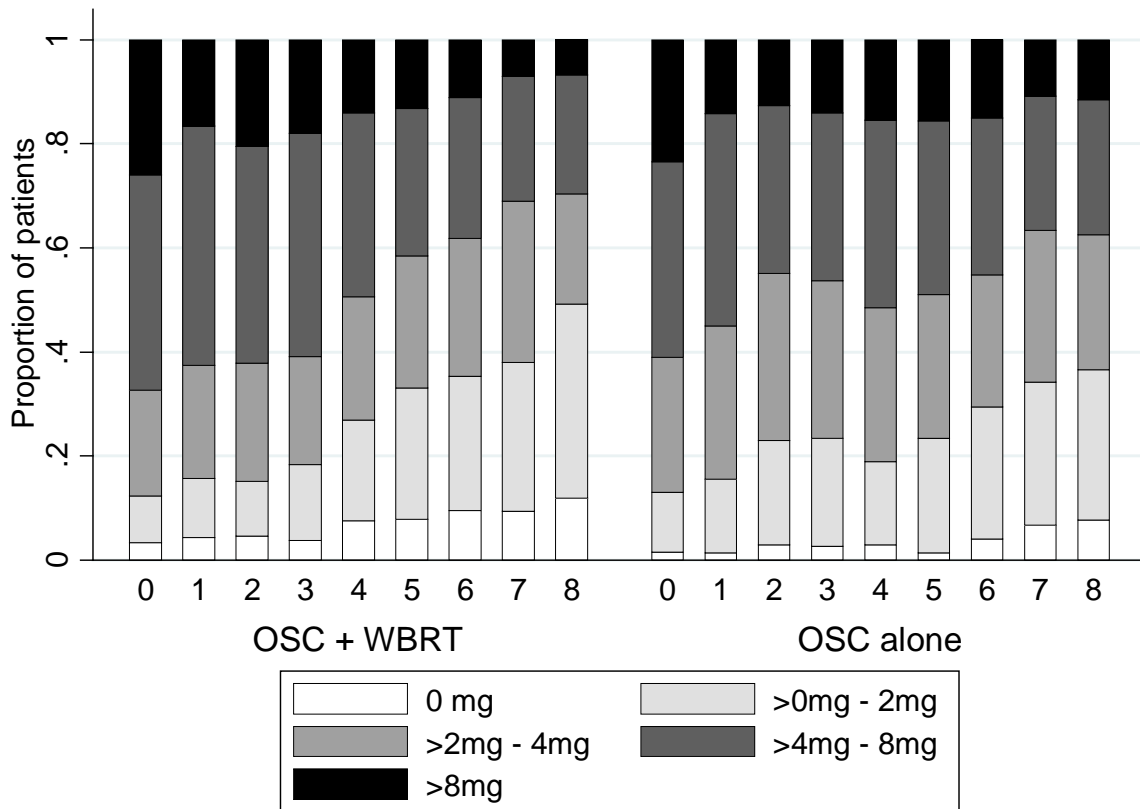
Subgroup	Value	Statistic	WBRT + OSC	OSC alone
	2	N	56	56
		Median OS	8.3	7.4
		95% CI	5.6, 10.7	6.3, 9.0
	3	N	28	22
		Median OS	9.6	10.1
		95% CI	5.3, 13.1	4.7, 13.7
	4	N	15	20
		Median OS	6.4	11.7
		95% CI	4.1, 13.7	4.7, 19.0
	5+	N	85	89
		Median OS	11.1	8.1
		95% CI	8.1, 13.0	6.4, 9.7
RPA	I	N	22	8
		Median OS	19.9	8.1
		95% CI	13.1, 48.7	1.6, 34.3
	II	N	145	156
		Median OS	11.3	9.0
		95% CI	9.6, 13.0	8.3, 11.0
	III	N	100	102

Subgroup	Value	Statistic	WBRT + OSC	OSC alone
		Median OS	5.7	5.7
		95% CI	5.0, 7.1	4.4, 7.3
GPA	3.5 – 4.0	N	5	2
		Median OS	11.9	7.6
		95% CI	1.0, Undef	7.6, Undef
	2.5 – 3.0	N	39	40
		Median OS	18.4	8.9
		95% CI	10.1, 23.4	8.0, 12.9
	1.5 – 2.0	N	109	104
		Median OS	8.1	8.0
		95% CI	6.7, 10.7	6.6, 9.3
	0.0 – 1.0	N	111	123
		Median OS	8.7	8.0
		95% CI	5.9, 11.1	6.4, 10.1

Note: KPS = Karnofsky Performance Status; RPA = Recursive Partitioning Analysis; GPA = Graded Prognostic Assessment.

Note: P-values for interactions between factors and treatment arm are: Sex 0.4477; Age group 0.0061(0.0043 for age as linear trend); KPS 0.0964 (0.2379 for KPS as linear trend); Extra-cranial metastases 0.1719; Primary NSCLC 0.0941; Number of brain metastases 0.3377; RPA 0.2762 (0.0834 for RPA as linear trend); GPA 0.2642 (0.0812 for GPA as linear trend).

**Supplementary Figure S1: Dexamethasone use over time.**



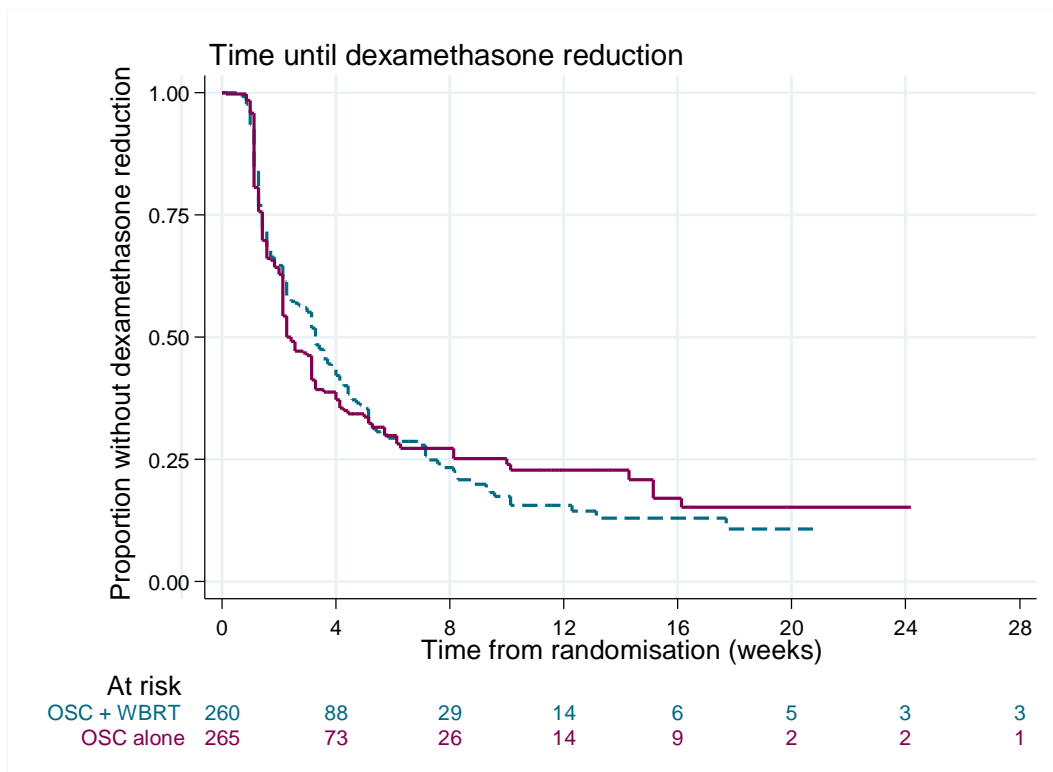
Notes: Week 0 = dose received at baseline.

Number of patients with data at each timepoint (WBRT, OSC):

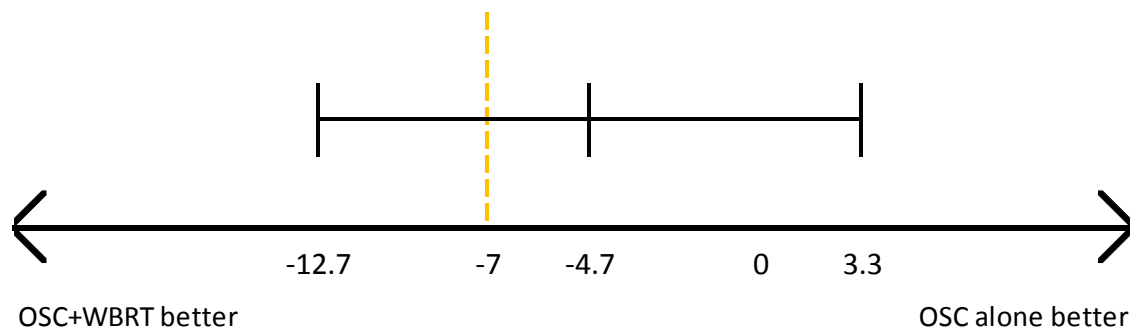
Week 0 (269, 269); week 1 (211, 218); week 2 (219, 205); week 3 (212, 192); week 4 (186, 175); week 5 (166, 141); week 6 (136, 126); week 7 (129, 120); week 8 (118, 104).

Proportions are calculated from the number of patients with non-missing data.

Supplementary Figure S2: Time to dexamethasone reduction



**Supplementary Figure S3: Difference in QALY days, with 90% confidence interval.**



Note: QALY = Quality Adjusted Life Years; OSC = Optimal Supportive Care; WBRT = Whole Brain Radiotherapy.

Note: -4.7 days represents the estimate of the difference in QALYs. -12.7 days and 3.3 days represent the upper and lower limit of the 90% confidence interval for the difference in QALYs (OSC alone – OSC+WBRT).

Note: The yellow dashed vertical line represents the pre-specified non-inferiority boundary of seven days.

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Russells Hall Hospital (Pek Keng-Koh, Daniel Bull, Lesley Edwards, Simon Grumett, Kathy Harrow, Karen Kanyi, Lucy Smith, Sara Smith);

Scarborough General Hospital (Rachael Barton, Alison Ames, Donna Anderson, Fizzah Asif, Chloe Box, Joanne Fletcher, Tracey Hawkes, Sacha Honour, Sarah Kent, Polly Needs, Anne Nunn);

South Tyneside District Hospital (Liz Fuller, Joanne Battenbo, Penny Borgen, Alison East, Georgi Georgiev, Chris Jones, Gourdarz Mazdai, Rhona McMenemin, Judith Moore, David Stock, Irene Underwood, Michael Walton);

Southampton General Hospital (Chris Baughan, Adityanarayan Bhatnagar, Andrew Bates, Stefan Brodmann, Lynne Dando, Sajid Durrani, Clare Green, Julie Gwilt, Peter MW Johnson, Vladimir Malykh, Helen Martin, Julie Morris, Christian Ottensmeier, Jocelyn Walters);

Southend University Hospital (Mandip Khaira, Jolly Barber, Olivia Chan, Tim Crook, Julia Jonasi, Katrina Maitland, Sreekanth Palvai, Jan Prejbsiz, Anne CR Robinson, Heather Shires, Colin Trask);

Southern General Hospital (Claire Paterson, Karen Bell, Jackie Byers, Scott Davidson, Janet Devlin, Grainne Dunn, Laura Ferguson, Fiona Maclean, Donna McWilliam);

St Bartholomews Hospital (London) (Paula Wells, Denise Andrews, Marina Baccarini, Nanette Bech-Nielsen, Charlotte Coyte, Dean Fennell, Shahanara Ferdous, Emma Foster, John Gribben, Paul Hillman, Janet Kiff, Antonia Koutsoukou, Samuel Mugari, Alastair Nicholson, Jude Nixon, Catherine Norman, Melanie Scott, Andrew Shaw, Jeremy Steele, Peter Szlosarek, Jonathan Teague);

St James University Hospital (Leeds) (Rob Turner, Gemma Austin (nee Glover), Marilyn Bond, David Bottomley, Rutger Clarke, Kevin Franks, Lynda Garbutt, Georgina Gerrard, James Goulding, Irene Greenwood, Fiona Halstead, Jillian Hanson, Paul Hatfield, Helen Jones, Julie Mansell, Clive Mulatero, Fatima Murad, Fiona Richards, Angela Scotland, Matt Seymour, Mike Snee, Rob Stuart, Johanne Sugden, Kay Tobin);

Stobhill Hospital (Richard D Jones, Karen Bell, Geri Hamilton, Sai Juan Jia, Audrey Leonard, Robert Milroy, Kirsteen Stuart, Claudia Turley);

Tameside General Hospital (Margaret Harris, Michelle Blodwell, Shirley Cocks, Martina Coulding, Edith Curran, Stephanie Ridgway);

Torbay District General Hospital (Nicole Dorey, Nigel Bailey, Victoria Bell, Peter Bliss, Martyn Blundell, Jo Blurton, Geoffrey Cogill, Jenny Cook, Donna Cuffe, Claire Fairfax, Andrew Goodman, Helen Greedus, Ingrid Koehler, Fiona Roberts, Lorraine Thornton, Elizabeth Toy, Linda Welsh, Nick Young);

University Hospital Aintree (John Littler, Lucy Berresford, Chinnamani Eswar, Julie Griffiths, Maria Guerin, Paul Hill, Linda Kearns, Lorraine Lancaster, Haley McCulloch, Leigh Pauls, Shirley Pringle, Sarah Rose, Asha Sivapalasantharam);

University Hospital Coventry and Warwickshire (Mark Hocking, Maggie Brown, Sue Elwell, Sarah Evans, Kate Field, Alison Franks, Julia Gaston, Sandeep Gill, Bob Grieve, Donna Halliman, Joanna Hamilton, Lesley Hayward, Caroline Humber, Judith Lake, Rosaleen Laverick, Gemma Mansell, Hayley Morton, Efosa Omigie, Pritpal Panesar, Elaine Simmons, Melanie Sinfield, Justin Somanathan, Emily Steventon, Frances White, Kimberley White, Linda Wimbush);

University Hospital Llandough (Jason Lester, Sarah Bridges, Mim Evans, Alison Kelly, Fergus Macbeth, Barbara Moore, Zoe Whale);

University Hospital of North Durham (Rhona McMenemin, Jean Dent, Julie Elliot, Julie Elliott, Jayne McClelland, Lorna Morgan, Dorothy Turnbull, Lisa Wayman, Sarah Welsh);

Velindre Hospital (Jason Lester, Caroline Bobart, Sarah Bridges, Michael Button, Rebecca Cloudsdale, Alison Edwards, Mim Evans, Claire Heymann, Alison Kelly, Fergus Macbeth, Tim Maughan, Barbara Moore, Lynda Penketh, Sara Shankland, Stephen Slade, Helen Stanton, Caroline Vitolo);

Victoria Infirmary (Jonathon Hicks, Karen Bell, Jackie Byers, Janet Devlin, Laura Ferguson, Donna McWilliam, Emma Moody, Rebecca Muirhead, Claire Paterson, Joseph Sarvesvaran, Nicola Steele, Claudia Turley);

Wansbeck General Hospital (Paula Mulvenna, Andrew Johnston, Tessa Lowes, Jeanette Raine, Zarine Razvi, Julia Scott, Marie Todd, Steve Williamson);

Warwick Hospital (Alison Franks, Caroline Humber, Mark Hocking, Michelle Faupel, Lesley Gotschy, Joanna Hamilton, Lyn Hartwell, Julia Jones, Helen Millage, Emily Noonan, Elaine Simmons, Frances White);

West Suffolk Hospital (Yvonne Rimmer, Cherri Blades, Gill Brett, Deborah Clements-Dimmock, Mark Heath, Daniel Patterson, John Raja Ravendar, Christine Watkins);

Weston General Hospital (Waheeda Owadally, Marjorie Tomlinson, Hannah Berry, Christine Graham, Axel Walther, Debbie Coles, Donna Cotterill, Harvey Dymond, Serena Hilman, Sarah Kidd, Denise Leighton-Price, Hugh Lloyd-Jones, Vivienne Pixton, Dawn Simmons, Tom Wells);

Weston Park Hospital (Patricia Fisher, Mymoona Alzouebi, Emma Bates, Laura Borrill, Lesley Bruce, Jaseela Chiramel, Robert Coleman, Sarah Danson, Yvonne Deeley, Julia Disney, Linda Evans, Bernie Foran, Clare Garner, Kate Gibbins, Matthew Hatton, Elizabeth Hodgkinson, Patrick Joyce, Peter Kirkbride, Caroline Lee, Jayaram Mohanamurali, James Swinscoe, Mark Trigg, Penella Woll, Helen Wood, Robin Young);

Whipps Cross University Hospital (Paula Wells, Denise Andrews, Charlotte Coyte, Elizabeth Croydon, Patricia Danaswamy, Emma Foster, Andrew Gillian, Memory Kazingizi, Fiona McKirdy, Samuel Mugari, Denisa Murati, Alastair Nicholson, Thompson Olaoni, Jonathan Teague);

William Harvey Hospital (Russell Burcombe, Thomas Bird, Tracy Boakes, Jane Brown, Julie Buckley, Mathilda Cominos, Denise Crawford, Stuart Drakeley, Susan Drakeley, Louise Gladwell, Coral Greenstreet, Joan Idris, Kathryn Lees, Margaret Lipsham, Sharon Middleton, Rakesh Raman, Karen Robinson, Joanne Severn, Paula Whichelo, Marian Wood, Linda Wray);

Worcestershire Royal Hospital (Mark Churn, Lisa Capaldi, Susan Anderson, Eleanor Andrews (nee Moore), Charlie Candish, Kristy Cleary, Sue Davies, David Farrugia, Janet Forkes, Linda Harris, Jayne Tyler, Sue Wronski);

Worthing Hospital (Nick Adams, Jo Congleton, Angela Dunne, Celia Gonzales, Sarah House, Lynda Huggins, Jayne Hughes, Helen Jones, Geoff Newman, Faye Oliver, Susan Rockall, Kathrine Steele, Nikki Turner, Paula Wakelen);