

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
<p>Author & Year: Howard et al, 2005³⁸⁵</p> <p>Study design: RCT</p> <p>Setting: Headache clinic in secondary care, London</p> <p>Duration of follow-up: 1 year</p>	<p>Patient group: Patients with chronic daily headache</p> <p>Inclusion criteria: Consecutive English-speaking patients who fulfilled the criteria for chronic daily headache (CDH); at least 15 days per month of headache for >6 months, including tension-type headache, migraine and secondary headache due to excessive medication consumption, presenting as new patients to the headache clinic at King's College Hospital in London.</p> <p>Exclusion criteria: Clinical justification for neuroimaging (with the exception of solely providing reassurance). Medical contraindication to an MRI scan.</p> <p>All patients N: 150 Age (mean): 38.1 (S.D. 12.4) years Drop outs: 8, but unclear HADS positive: 66/150 (44%)</p> <p>Group 1 (offered scan)</p>	<p>Group 1 Received an offer of a screening MRI scan using a sagittal localiser image followed by a double echo axial series.</p> <p>Group 2 No scan / treatment as usual</p> <p>All patients Asked to take part in interviews and follow up questionnaires with data from primary care case notes.</p> <p>Given a letter providing information on CDH. Completed a semi-structured interview for their medical and psychiatric history.</p> <p>Completed the following scales: HADS (hospital anxiety and depression scale) Visual analogue scales (VAS) of level of worry about health (0-100) and level of</p>	<p>Resource use - GP Number of patients using services during year following randomisation</p>	<p>Group1: 67/68 (99%) Group 2: 66/69 (96%) Relative risk: 0.99 * 95% CI: 0.88-1.11 * p value: 0.619 (0.84*)</p>	<p>Funding: The Wellcome Trust</p> <p>Limitations: Randomisation unclear. Patients swapped groups. Allocation concealment unclear. Single-blind (assessor only). Response rate was lower than expected which meant there was a lack of statistical power for some of the outcome measures. 1/3 of HADS positive patients not offered a scan had scans elsewhere in the following year. Incomplete reporting of data.</p> <p>Additional outcomes: Likert five point scales for anxiety about serious underlying illness. Revised illness perception questionnaire (IPQ-R). Medical outcome study</p>
			<p>Resource use - neurologist Number of patients using services during year following randomisation</p>	<p>Group1: 1/68 (1.5%) Group 2: 17/69 (25%) Relative risk: 0.06 * 95% CI: 0.01-0.42 * p value: <0.001 (0.005*)</p>	
			<p>Resource use - psychiatrist/therapist Number of patients using services during year following randomisation</p>	<p>Group1: 1/68 (1.5%) Group 2: 8/69 (12%) Relative risk: 0.12 * 95% CI: 0.02-0.95 * p value: 0.033 (0.04*)</p>	
			<p>Resource use – outpatient Number of patients using services during year following randomisation</p>	<p>Group1: 30/68 (44%) Group 2: 32/69 (46%) Relative risk: 0.91* 95% CI: 0.62-1.34 * p value: 0.864 (0.64*)</p>	
			<p>Resource use – other imaging Number of patients using services during year following randomisation</p>	<p>Group1: 13/68 (19%) Group 2: 21/69 (30%) Relative risk: 0.60* 95% CI: 0.33-1.11* p value: 0.166 (0.11*)</p>	
			<p>Resource use – tests Number of patients using services during year</p>	<p>Group1: 21/68 (31%) Group 2: 29/69 (42%) Relative risk: 0.71*</p>	

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	<p>N: 76 Age (mean):37 (11.4%) Drop outs: not clear, 5 did not have scan</p> <p>Group 2 (not offered scan) N: 74 Age (mean): 40 (13.2) Drop outs: unclear, 3 demanded a scan.</p>	<p>illness belief (0-100)</p> <p>Likert five point scales of anxiety about serious underlying illness.</p> <p>Health anxiety questionnaire (HAQ) of 21 questions with 4 subscales.</p> <p>Service use over a retrospective 1 year period prior to consultation (Client Service Receipt Inventory).</p> <p>Revised illness perception questionnaire (IPQ-R).</p> <p>Medical outcome study short form 36 (SF-36).</p> <p>Headache diary 6 weeks before the consultation and headache index calculated.</p> <p>All patients received usual clinical care: explanation of symptoms, verbal reassurance of no serious pathology and CDH advice.</p>	<p>following randomisation</p> <p>Resource use – inpatient care Number of patients using services during year following randomisation</p> <p>Resource use – other services Number of patients using services during year following randomisation</p> <p>Resource use – sick notes Number of patients using services during year following randomisation</p> <p>Change in anxiety and depression VAS worry (at 1 year, scan-no scan) (n Gp1: 54, Gp2: 42)</p> <p>Change in anxiety and depression HAQ health, worry and preoccupation (at 1 year, scan-no scan) (n Gp1: 48, Gp2: 34)</p> <p>Change in anxiety and depression</p>	<p>95% CI:0.44-1.12* p value: 0.215 (0.14*)</p> <p>Group1: 5/68 (7%) Group 2: 10/69 (14%) Relative risk: 0.49* 95% CI:0.17-1.36* p value: 0.274 (0.17*)</p> <p>Group1: 6/68 (9%) Group 2: 6/69 (9%) Relative risk: 0.97* 95% CI:0.33-2.88* p value: 1 (0.96*)</p> <p>Group1: 6/68 (9%) Group 2: 7/69 (10%) Relative risk: 0.83* 95% CI: 0.29-2.37* p value: 1 (0.73*)</p> <p>Adjusted difference: -4.47 95% CI:-15.27 to 6.33 SE: 5.51 †</p> <p>Adjusted difference: 0.22 95% CI:-1.26 to 1.70 SE: 0.76 †</p> <p>Adjusted difference: 0.31 95% CI:-0.84 to 1.45</p>	<p>short form 36 (SF-36), data not reported.</p> <p>Notes: CDH defined as: at least 15 days per month of headache for more than 6 months (which can include tension type headache, migraine, and secondary headache due to extensive medication consumption).</p> <p>Headache index= no. of hours with headache x intensity / no. of days recorded.</p> <p>* Based on ITT analysis in paper – other data reported here is available case analysis.</p> <p>†calculated by NCGC</p>

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			HAQ fear of illness (at 1 year, scan-no scan) (n Gp1: 50, Gp2: 33)	SE: 0.58 †	
			Change in anxiety and depression HAQ reassurance seeking behaviour (at 1 year, scan-no scan) (n Gp1: 50, Gp2: 35)	Adjusted difference: -0.39 95% CI: -0.93 to 0.16 SE: 0.28 †	
			Change in anxiety and depression HAQ life interference (at 1 year, scan-no scan) (n Gp1: 51, Gp2: 33)	Adjusted difference: -0.20 95% CI: -1.12 to 0.72 SE: 0.47 †	
			Incidental neurological findings (%)	97% normal 2 abnormal (a posterior fossa arachnoid cyst and a hypothalamic signal flair, neither clinically significant).	

Abbreviations: NR=not reported, NA=not applicable, M/F=male/female, N=total number of patients randomised, SD=Standard deviation, SE=Standard error, ITT=Intention to treat analysis, CDH=chronic daily headache, HADS=hospital anxiety and depression scale, VAS=Visual analogue scale