

Supplementary Online Content

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This supplementary material has been provided by the authors to give readers additional information about their work.

eMethods 1. Clinical Trial Investigators and Sites, Bariatric Surgery Pathway Team, Patient Identification Centers, and Study Oversight Committees

Trial Investigators

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Study oversight committees

We thank all the members of the study oversight committees for their valued contributions.

The IIH:WT Trial Steering Committee; the Data Monitoring and Ethics Committee and the Trial Management Group.

eMethods 2. Community Weight Management Intervention, Bariatric Surgery Pathway, and Hierarchical Regression Analysis

Community weight management intervention

WeightWatchers™ program was chosen as the community weight management intervention (CWI) because it had superior weight loss¹, was the best attended and most cost-effective². Participants in the CWI arm were given exemption vouchers for 52 consecutive and specified weeks of their local WeightWatchers™ group with access to WeightWatchers™ online and mobile tools for 12 months. Vouchers provided 12 sessions at baseline, 3, 6 and 9 months.

Bariatric surgery pathway

The bariatric surgery pathway participants were screened to ensure their suitability, initially for medical and psychological assessment in the weight management clinic. This assessment continued for as long as thought appropriate, as per routine care. Once suitable, the case was discussed in the joint multi-disciplinary meeting, prior a group session for education regarding surgery. The participant then attended a consultant bariatric surgeon and was given a date for surgery. Twelve weeks was permitted for further consideration of the procedure if required. The standard patient pathway was envisioned to take approximately 4 months. The choice of surgical intervention was decided between the surgeon and participant, based on the participant's health and preference. These included laparoscopic adjustable gastric banding, laparoscopic Roux-en-Y gastric bypass or laparoscopic sleeve gastrectomy.

Hierarchical regression analysis

Initially, hierarchical regression models were generated, with data for both eyes for all patients analyzed in one model, using group structure to distinguish between the eyes. Models contained population-level terms (i.e. terms that apply to each experimental unit) to reflect: 1) the mean baseline value (i.e. the intercept); 2) the mean change from baseline associated with each assessment time (i.e. time as a factor variable); 3) the extra mean change from baseline associated with each assessment time in the experimental arm (i.e. the interaction of treatment allocation and time as a factor variable). Additionally, hierarchical regression models contained random effects (i.e. terms that are specific to each experimental unit) to reflect the random deviations from the population-level mean value at baseline (i.e. random intercepts).

eResults. Relevant Medication Changes Over the Course of the Clinical Trial

Headache preventative medication was taken by 27% (18/66) of all patients at enrolment. This reduced markedly amongst the bariatric surgery arm from 36% (12/33) at baseline to 7% (2/30) at 12 months, compared with little difference in the CWI arm from baseline 18% (6/33) to 21% (6/29) at 12 months. Acetazolamide was taken by 29% (19/66) of all patients at enrolment. The number of patients using acetazolamide reduced amongst those in the bariatric surgery arm from 24% (8/33) to 3% (1/30) with a mean daily dose change from 781mg (471.3) to 500mg (standard deviation [SD] 0) compared with the CWI arm whose numbers using acetazolamide reduced from 33% (11/33) to 28% (8/33) with a mean daily dose change from 909mg (SD 550.8) to 844mg (SD 498.9). Topiramate was used by 12% (4/33) in the bariatric surgery arm at baseline. All had discontinued by 12 months, whilst in the CWI arm 6% (2/33) topiramate use increased to 10% (3/29) by 12 months. Those taking other diuretics were 3% (1/33) in bariatric surgery arm and 6% (2/33) in the CWI arm at baseline. By 12 months, 3% (1/30) were using a diuretic in the bariatric surgery arm and 10% (3/29) in the CWI arm. There were no significant differences in the use of antihypertensive medications or hormonal contraception.

eTable 1. Inclusion and Exclusion Criteria of the IIH:WT

	Criterion
Inclusion	Female patients with IIH aged between 18 and 55 years, diagnosed according to the Friedman Jacobson criteria, ¹ who have active disease [papilloedema (Frisén ² grade ≥ 1 in at least one eye), significantly raised LP OP ≥ 25 cmCSF] of over 2 months' duration and no evidence of venous sinus thrombosis (MRI or CT and venography as noted at diagnosis)
	Body mass index of ≥ 35 kg/m ² .
	Have previously tried other appropriate non-surgical treatments to lose weight but have not been able to achieve or maintain adequate, clinically beneficial weight loss for at least 6 months.
	Able to give informed consent.
Exclusion	Age <18 or >55 years.
	Pregnancy, or planning pregnancy.
	Significant comorbidity, Cushing's syndrome, Addison's disease or the use of oral or injected glucocorticoid therapy.
	Previously undergone optic nerve sheath fenestration
	Definite indication for or contraindication against surgery or dieting
	Have a specific medical or psychiatric contraindication for surgery, including drug misuse, eating disorder or major depression (suicidal ideation, drug overdose or psychological admission in the last 12 months).
	Previous bariatric surgery
	Inability to give informed consent, for example, due to cognitive impairment.

References to eTable 1:

1. Friedman DI, Liu GT, Digre KB. Revised diagnostic criteria for the pseudotumor cerebri syndrome in adults and children. *Neurology*. 2013; 81(13):1159-1165.
2. Frisen L. Swelling of the optic nerve head: a staging scheme. *J Neurol Neurosurg Psychiatry*. 1982;45(1):13-18.

eTable 2. IIH:WT Schedule of Events

Outcome	Measure	Baseline	3 months	6 months	Postoperative	12 months (primary endpoint)	24 months	60 months
Intracranial pressure	Lumbar puncture opening pressure	x			x	x	x	x
Clinical measures	Body mass index, blood pressure, waist/hip, fat mass, medication use	x	x	x	x	x	x	x
Idiopathic Intracranial Hypertension symptoms	Pulsatile tinnitus, visual loss, diplopia, visual obscurations	x				x	x	x
Visual function	Visual acuity, contrast sensitivity, colour assessment	x				x	x	x
	Humphrey visual field (24-2)	x				x	x	x
Papilledema grade	Optical coherence tomography	x				x	x	x
	Retinal photographs	x				x	x	x
Headache	HIT-6, headache diary	x				x	x	x
Quality of life	EQ-5D-5L, ICECAP-A, SF-36 v1, HADS	x				x	x	x
Health economics	Resource use questionnaire	x				x	x	x

HIT-6 = Headache impact test-6. EQ-5D-5L= ICECAP-A= SF-36v1=, HADS=Hospital anxiety and depression score.

eTable 3. Secondary Outcome: Headache

Differences in headache and visual function outcomes were not significant at 12- or 24-months (eTables 3 and 4). Exploratory analysis noted a greater improvement in monthly headache days, headache severity and HIT-6 scores in the bariatric surgery arm between baseline and 12-months (eTable 3).

	Baseline	12 months	24 months	Difference baseline to 12 months	Difference baseline to 12 months	Difference baseline to 24 months	Difference between arms at 12 months	Difference between arms at 24 months
					Hierarchical regression			
					Mean (SE); 95% CI, p			
Headache disability (HIT-6)								
Community weight management intervention	64.3 (8.6), 32	59.7 (12.4), 26	60.2 (10.9), 23	-6.2 (9.8), 28	-5.3 (1.9); (-9.1, -1.5), p=0.006	-5.7 (2.0); (-9.7, -1.8), p=0.004	-1.4 (2.6); (-6.6, 3.8), p=0.603	-1.4 (2.8); (-7.0, 4.1), p=0.610
Bariatric surgery	65.1 (6.0), 33	57.5 (9.1), 29	56.5 (13.0), 23	-7.4 (8.6), 29	-7.5 (1.9); (-11.1, -3.9), p<0.001	-8.0 (2.0); (-11.9, -4.0), p<0.001		
Monthly headache days								
Community weight management intervention	22.5 (7.8), 31	16.7 (11.8), 24	15.8 (11.1), 21	-6.3 (9.9), 23	-5.9 (2.2); (-10.2, -1.6), p=0.007	-7.4 (2.3); (-11.9, -2.9), p=0.001	-3.2 (2.8); (-8.6, 2.2), p=0.247	-2.9 (3.0); (-8.7, 2.9), p=0.328
Bariatric surgery	22.0 (8.3), 32	13.2 (11.4), 29	11.8 (11.8), 24	-8.1 (10.5), 28	-8.5 (2.0); (-12.5, -4.5), p<0.001	-9.7 (2.2); (-13.9, -5.5), p<0.001		
Monthly analgesic frequency								
Community weight management intervention	14.1 (9.4), 31	10.2 (10.5), 24	9.0 (9.5), 21	..	-3.7 (2.1); (-7.9, 0.5), p=0.085	-6.0 (2.2); (-10.4, -1.6), p=0.008	-3.0 (2.6); (-8.1, 2.2), p=0.257	1.2 (2.8); (-4.3, 6.7), p=0.665
Bariatric surgery	10.6 (8.5), 32	7.3 (9.1), 29	9.3 (11.0), 24	..	-3.1 (2.0); (-7.0, 0.9), p=0.125	-1.2 (2.1); (-5.3, 2.9), p=0.570		
Headache severity (VRS 0-10)								
Community weight management intervention	5.0 (2.1), 31	4.0 (3.3), 24	3.8 (3.0), 21	-1.1 (2.5), 22	-1.0 (0.6); (-2.2, 0.2), p=0.110	-1.5 (0.6); (-2.7, -0.2), p=0.023	-0.9 (0.7); (-2.3, 0.6), p=0.231	0.2 (0.8); (-1.3, 1.7), p=0.796
Bariatric surgery	5.0 (1.9), 32	3.2 (2.6), 29	3.8 (3.1), 24	-1.6 (2.7), 28	-1.8 (0.6); (-2.9, -0.7), p=0.002	-1.2 (0.6); (-2.4, 0.0), p=0.045		

CI=confidence interval. SD=standard deviation. SE=standard error.

eTable 4. Secondary Outcome: Visual Data (Worst Eye)

	Base line	12 months	24 months	Difference baseline to 12 months	Difference baseline to 12 months	Difference baseline to 24 months	Difference between arms at 12 months	Difference between arms at 24 months
	Mean (SD), n			Mean (SD); 95%CI, p	Hierarchical regression Mean (SE); 95%CI, p			
logMar visual acuity								
Community weight management intervention	0.0 (0.2), 33	0.0 (0.2), 28	0.0 (0.2), 21	-0.02 (0.20)	0.0 (0.1); (-0.1, 0.1), p=0.985	0.0 (0.1); (-0.1, 0.1), p=0.661	0.0 (0.1); (-0.1, 0.1), p=0.598	0.0 (0.1); (-0.1, 0.1), p=0.988
Bariatric surgery	0.0 (0.2), 33	0.0 (0.2), 30	-0.1 (0.1), 24	-0.08 (0.24)	-0.1 (0.1); (-0.2, 0.0), p=0.058	-0.1 (0.1); (-0.1, 0.0), p=0.120		
Log contrast sensitivity								
Community weight management intervention	1.7 (0.1), 33	1.7 (0.1), 28	1.7 (0.1), 21	..	0.0 (0.1); (0.0, 0.1), p=0.630	0.0 (0.1); (0.0, 0.1), p=0.584	0.0 (0.1); (-0.1, 0.0), p=0.411	0.0 (0.1); (-0.1, 0.1), p=0.951
Bariatric surgery	1.7 (0.1), 33	1.7 (0.1), 29	1.7 (0.1), 24	..	0.0 (0.1); (0.0, 0.1), p=0.463	0.1 (0.1); (0.0, 0.1), p=0.066		
Perimetric mean deviation, dB (HVF 24-2 SITA standard)								
Community weight management intervention	-3.5 (3.8), 33	-2.0 (2.3), 29	-2.1 (2.8), 22	1.2 (2.6)	1.3 (0.5); (0.3, 2.3), p=0.010	1.5 (0.6); (0.4, 2.6), p=0.010	-0.5 (0.8); (-2.0, 1.0), p=0.526	0.1 (0.8); (-1.5, 1.8), p=0.863
Bariatric surgery	-3.6 (3.5), 32	-2.8 (2.6), 29	-2.2 (2.2), 24	1.1 (2.7)	1.0 (0.5); (-0.1, 2.0), p=0.064	1.8 (0.6); (0.7, 2.8), p=0.002		
Optical Coherence Tomography retinal nerve fibre layer in more affected (worst) eye (µm)								
Community weight management intervention	161.7 (95.7), 32	111.8 (33.1), 28	107.4 (31.9), 22	-56 (88.3), 27	-50.5 (15.9); (-81.7, -19.3), p=0.001	-53.0 (17.1); (-86.6, -19.4), p=0.002	-8.1 (17.3); (-41.9, 25.8), p=0.641	-7.7 (19.6); (-46.1, 30.7), p=0.695
Bariatric surgery	148.8 (99.1), 32	103.0 (27.4), 29	103.0 (27.3), 22	-43 (107.3), 29	-45.3 (15.7); (-76.1, -14.5), p=0.004	-47.4 (17.1); (-80.9, -13.9), p=0.006		

All visual function measures are of worst eye. Negative values in the mean difference and adjusted mean difference favour surgical arm. SD=standard deviation. CI=confidence interval. HVF- Humphrey visual field.

eTable 5. IIH Symptoms, Baseline to 12 Months

There was no evidence of improvement in the IIH symptoms of pulsatile tinnitus, visual symptoms, diplopia and visual obscurations in either group (eTable 5).

	Baseline		12 months		Relative Risk* (95% CI)	p
	Community weight management	Bariatric surgery	Community weight management	Bariatric surgery		
Pulsatile Tinnitus						
Not experienced	8 (24)	9 (27)	11(38)	16(53)	0.76 (0.50 to 1.17)	0.2
Experienced	25 (76)	24 (73)	18(62)	14(47)		
Visual Loss						
Not experienced	10 (30)	8 (24)	15(52)	20(67)	0.69 (0.37 to 1.30)	0.2
Experienced	23 (70)	25 (76)	14(48)	10(33)		
Diplopia						
Not experienced	29 (88)	19 (58)	25(86)	26(87)	0.33 (0.07 to 1.67)	0.2
Experienced	4 (12)	14 (42)	4(14)	4(13)		
Visual Obscurations						
Not experienced	16 (48)	16 (48)	25(86)	23(77)	1.53 (0.54 to 4.35)	0.4
Experienced	17 (52)	17 (52)	4(14)	7(23)		
Headache						
Not experienced	1 (3)	2 (6)	6(21)	8(27)	0.98 (0.67 to 1.44)	0.9
Experienced	32 (97)	31 (94)	23(79)	22(73)		

Data are n(%) unless otherwise stated.*Adjusted for baseline IIH symptoms and acetazolamide use at entry (stratification variable). Relative risk less than 1 favours bariatric surgery.

CI = confidence intervals.

eTable 6. Quality of Life and Hospital Anxiety and Depression Scores

	Base line	12 month	24 month	Difference baseline to 12 months	Difference baseline to 24 months	Difference between arms at 12 months	Difference between arms at 24 months
	Mean (SD), n			Hierarchical regression mean (SE); 95%CI, p		Hierarchical regression mean (SE); 95%CI, p	
Quality of Life							
Quality of life (SF-36) PCS summary							
Community weight management intervention	29.1 (12.2), 30	33.4 (14.8), 25	32.0 (13.8), 22	4.5 (2.6); (-0.5, 9.6), p=0.079	4.5 (2.8); (-0.9, 9.9), p=0.099	7.3 (3.6); (0.2, 14.4), p=0.043	10.4 (3.8); (3.0, 17.9), p=0.006
Bariatric Surgery	28.3 (13.4), 30	41.6 (14.0), 28	45.2 (12.0), 23	13.1 (2.5); (8.1, 18.0), p<0.001	16.2 (2.7); (10.9, 21.5), p<0.001		
Quality of life (SF-36) MCS summary							
Community weight management intervention	35.8 (10.2), 30	37.9 (12.0), 25	39.6 (12.6), 22	2.1 (2.4); (-2.6, 6.9), p=0.384	4.3 (2.6); (-0.8, 9.3), p=0.097	1.6 (3.2); (-4.6, 7.8), p=0.617	-0.5 (3.4); (-7.1, 6.1), p=0.876
Bariatric Surgery	39.7 (11.5), 30	39.8 (12.5), 28	39.8 (12.4), 23	-0.1 (2.4); (-4.7, 4.6), p=0.981	0.0 (2.6); (-5.0, 5.0), p=0.998		
Hospital anxiety and depression scores							
HADS -A							
Community weight management intervention	10.5 (4.6), 32	10.5 (5.2), 26	9.7 (5.6), 21	-0.1 (0.9); (-1.8, 1.6), p=0.925	-1.2 (0.9); (-3.1, 0.6), p=0.179	-1.1 (1.3); (-3.7, 1.5), p=0.405	-0.2 (1.4); (-3.0, 2.6), p=0.887
Bariatric Surgery	10.5 (5.1), 30	9.5 (4.8), 28	9.0 (5.8), 24	-1.1 (0.9); (-2.8, 0.6), p=0.202	-1.3 (0.9); (-3.1, 0.4), p=0.142		
HADS-D							
Community weight management intervention	7.9 (4.8), 32	7.3 (4.2), 27	7.0 (5.0), 22	-0.3 (0.8); (-1.9, 1.3), p=0.727	-1.5 (0.9); (-3.3, 0.2), p=0.082	-1.6 (1.2); (-4.0, 0.8), p=0.200	-1.5 (1.3); (-4.0, 1.1), p=0.268
Bariatric Surgery	7.6 (4.1), 31	6.2 (5.1), 30	4.8 (4.9), 24	-1.6 (0.8); (-3.1, 0.0), p=0.053	-2.7 (0.9); (-4.4, -1.0), p=0.002		

Data are mean (SD) or mean (SE).

SD=standard deviation. SE=standard error. CI=confidence interval. HIT-6 = Headache impact test-6. HADS=Hospital anxiety and depression score. SD = standard deviation. SE = standard error. SF-36 = 36-item short form survey.

eTable 7. Quality of Life Subscales as Measured by the SF-36

	Basel ine	12 mont hs	24 mont hs	Difference baseline to 12 months	Difference baseline to 24 months	Difference between arms at 12 months	Difference between arms at 24 months
Hierarchical regression mean (SE); 95%CI, p							
Physical functioning							
Community weight management	56.8 (26.1) , 31	62.6 (30.6) , 27	59.6 (30.1) , 23	4.1 (4.3); (- 4.2, 12.5), p=0.331	6.6 (4.5); (- 2.3, 15.5), p=0.144	20.2 (6.8); (6.9, 33.5), p=0.003	27.7 (7.2); (13.7, 41.8), p<0.001
Bariatric Surgery	56.6 (27.5) , 32	81.9 (22.9) , 29	92.6 (13.3) , 23	24.7 (4.1); (16.6, 32.8), p<0.001	34.6 (4.5); (25.8, 43.5), p<0.001		
Role limitation due to physical health							
Community weight management	28.1 (40.5) , 32	43.3 (47.2) , 26	46.7 (43.5) , 23	17.4 (8.8); (0.2, 34.6), p=0.047	24.4 (9.2); (6.4, 42.3), p=0.008		
Bariatric Surgery	36.4 (44.2) , 33	56.0 (43.6) , 29	57.3 (46.9) , 24	9.7 (8.4); (3.2, 36.2), p=0.019	21.1 (9.0); (3.5, 38.8), p=0.019	10.5 (11.8); (- 12.5, 33.6), p=0.371	5.0 (12.5); (- 19.4, 29.5), p=0.687
Role limitation due to emotional problems							
Community weight management	37.6 (43.7) , 31	51.3 (46.4) , 26	53.6 (46.9) , 23	13.2 (10.0); (- 6.4, 32.8), p=0.186	19.2 (10.4); (- 1.3, 39.6), p=0.066		
Bariatric Surgery	45.8 (45.4) , 32	57.5 (47.9) , 29	65.2 (44.4) , 23	11.6 (9.6); (- 7.2, 30.4), p=0.226	19.5 (10.4); (- 0.9, 39.9), p=0.060	5.9 (12.2); (- 18.0, 29.8), p=0.627	7.9 (13.1); (- 17.9, 33.6), p=0.550
Energy/Fatigue							
Community weight management	28.0 (18.2) , 32	33.7 (27.4) , 27	36.1 (23.9) , 23	5.7 (4.8); (- 3.8, 15.1), p=0.242	10.8 (5.1); (0.7, 20.8), p=0.035		
Bariatric Surgery	26.1 (20.8) , 33	49.0 (26.7) , 29	46.5 (28.8) , 24	22.4 (4.7); (13.2, 31.7), p<0.001	20.1 (5.0); (10.3, 30.0), p<0.001	14.9 (6.4); (2.4, 27.4), p=0.020	7.5 (6.8); (- 5.9, 20.9), p=0.275
Emotional well-being							
Community weight management	50.5 (23.6) , 32	56.0 (27.3) , 27	52.7 (27.8) , 23	5.3 (4.4); (- 3.4, 14.0), p=0.232	5.2 (4.7); (- 4.0, 14.5), p=0.268		
Bariatric Surgery	55.0 (26.3) , 33	59.2 (26.0) , 29	59.8 (29.4) , 24	3.1 (4.3); (- 5.4, 11.6), p=0.476	5.0 (4.6); (- 4.0, 14.1), p=0.277	2.3 (6.9); (- 11.2, 15.8), p=0.738	4.3 (7.2); (- 9.9, 18.5), p=0.550
Social functioning							
Community weight management	46.9 (8.4), 32	48.6 (6.3), 27	50.5 (10.3) , 23	1.8 (2.4); (- 2.9, 6.5), p=0.450	3.6 (2.5); (- 1.3, 8.5), p=0.145		
Bariatric Surgery	55.3 (11.3) , 33	50.4 (10.3) , 29	49.5 (8.6), 24	-4.9 (2.3); (- 9.4, -0.3), p=0.036	-5.9 (2.4); (- 10.7, -1.1), p=0.016	1.8 (2.5); (- 3.2, 6.7), p=0.482	-1.1 (2.7); (- 6.5, 4.2), p=0.680
Pain							

Community weight management	45.6 (26.2), 32	51.6 (30.4), 26	43.5 (30.0), 22	6.9 (5.9); (-4.6, 18.4), p=0.237	2.5 (6.2); (-9.7, 14.7), p=0.688		
Bariatric Surgery	42.9 (25.6), 32	62.4 (27.4), 28	61.5 (31.0), 24	18.4 (5.7); (7.2, 29.6), p=0.001	17.4 (6.1); (5.5, 29.3), p=0.004	8.4 (7.6); (-6.5, 23.3), p=0.267	11.9 (8.1); (-4.0, 27.7), p=0.143
General health							
Community weight management	34.1 (18.7), 32	39.4 (19.7), 27	32.8 (21.7), 23	4.7 (4.1); (-3.3, 12.7), p=0.247	0.3 (4.3); (-8.2, 8.7), p=0.949		
Bariatric Surgery	30.8 (17.6), 33	49.0 (24.0), 29	58.3 (27.8), 24	17.9 (4.0); (10.2, 25.7), p<0.001	26.4 (4.2); (18.1, 34.7), p<0.001	9.9 (5.6); (-1.2, 20.9), p=0.079	22.8 (6.0); (11.1, 34.6), p<0.001

Data are mean (SD) or mean (SE).

CI = confidence intervals. SD = standard deviation. SE = standard error. SF-36 = 36-item short form survey.

eTable 8. Serious Adverse Events at 12 and 24 Months

Time following randomisation	Community weight management intervention		Bariatric surgery		Total
	Related	Unrelated	Related	Unrelated	
0-12months	0	3 (3)	4	8 (6)	15
12-24months	1*	7 (4)	1	0 (0)	9
Total	1	10 (7)	5	8 (6)	24

Data are n. Those in brackets are the number of events that are a hospitalised episode of exacerbation of idiopathic intracranial hypertension.

* This participant had a headache following lumbar puncture as part of the trial, which was therefore assigned as a related serious adverse event headache. Adverse events are presented by Medical Dictionary for Regulatory Activities preferred term.