

Web appendix: Sensitivity, per protocol, and post hoc exploratory analyses

1. Analysis of effects of baseline group differences and missing data on primary outcome

METHODS

Sensitivity analysis was performed on the Vertigo Symptom Scale - Short Form at 12 weeks to adjust for differences in baseline measures and increase the number of subjects available for analysis by replacing missing data using multiple imputation.

RESULTS

Comparison of group baseline characteristics revealed differences in potentially important prognostic variables: age left school, gender, duration of dizziness, consultation with a health care professional in the past year and exceeding the HAD threshold for anxiety or depression. Sensitivity analysis adjusting for these imbalances and replacing missing data using multiple imputation was performed for on the Vertigo Symptom Scale - Short Form. At 12 weeks follow-up, there was an adjusted mean difference compared with routine care of -2.15 (-4.23 to -0.09, $P=0.041$) in the booklet with telephone support group and an adjusted mean difference of -0.73 (-2.63 to 1.17, $P=0.451$) in the booklet self-management group. At 1 year follow-up, there was an adjusted mean difference compared with routine care of -2.55 (-4.77 to -0.32, $P=0.025$) in the booklet with telephone support group and an adjusted mean difference of -2.54 (-4.51 to -0.56, $P=0.012$) in the booklet self-management group.

2. Per protocol analysis

METHODS

Participants were defined as 'per protocol' if they reported carrying out the rehabilitation exercises for as long as recommended, i.e. at least nine weeks or until their symptoms resolved (if this was sooner). The per protocol analysis was an ANCOVA comparing VSS-SF scores at 12 weeks (controlling for baseline VSS-SF scores) in those who were and were not per protocol.

RESULTS

Per protocol analysis confirmed better outcomes in those who reported full adherence to the treatment programme at 12 weeks, with an adjusted mean difference compared with routine care of -2.94 (-5.00 to -0.89, $P=0.005$) in the booklet with telephone support group and a mean difference of -3.38 (-5.59 to -1.17, $P=0.003$) in the booklet self-management group.

3. Cost-effectiveness sensitivity analyses

METHODS

We carried out a number of sensitivity analysis to investigate the effects of assumptions made during the analysis of cost-effectiveness data. These were:

- a. The base-case analysis assumed that providing the booklet was costless. We tested the effect of assuming that 5 minutes of GP time would be required to provide and explain the booklet.
- b. Our base-case analysis was carried out on a complete case analysis of 235 participants. The main source of missing data was incomplete EQ5D values leading

to inability to estimate QALYs. We imputed missing QALY values in order to analyse a larger sample of patients (333).

- c. Our base-case analysis used NHS costs only, we also carried out a sensitivity analysis where we included a cost for participant time spent completing exercises.

See Table 9 for unit costs used for all parameters.

Table 9. Unit costs used for all cost parameters

Cost item	Unit cost	Source
GP home visits	108	PSSRU
GP in surgery	32	PSSRU
Telephone conversation with GP	20	PSSRU
Practice nurse	12	PSSRU
Counsellor	71	PSSRU
Outpatient visits	85	NHS ref costs
A&E	111	NHS ref costs
Audiologist	57.4	NHS ref costs
Physiotherapist	20.84	
Private doctor	85	NHS ref costs
Inpatient stay	2849	NHS ref costs
Medicines		BNF
Telephone conversation with study therapists	12.94865	Various
Cost of booklet	0.34	Study data
		Dept of
Cost per hour of time	5.79	transport

RESULTS

Including the cost of GP time increased costs by approximately £14. The booklet self-management group no longer dominated routine care. ICERs were £346 and £1292 per QALY for booklet self-management compared to routine care and telephone support compared to booklet self-management respectively. Imputing missing data had very little effect; the routine care group was still dominated. Compared to booklet self-management alone telephone support generated QALYs at a cost of £1451 per QALY. Including the cost of participant time to complete exercises increased ICERs to £997 and £1488 (booklet self-management group compared to routine care, and telephone support group compared to booklet self-management respectively). In all three sensitivity values there were only small changes to results with no changes to the conclusions, i.e. the intervention groups still appeared cost-effective compared to routine care.

4. Post hoc exploratory analyses

METHODS

For the comparisons between treatment groups, all continuous outcomes were evaluated using ANCOVA, adjusting for the level of the relevant outcome variable at baseline as well as baseline symptom score (the stratification variable). Binary group outcomes were compared using logistic regression, also adjusting for baseline symptom score. Independent t-tests were used to compare intervention groups on all measures of adherence to rehabilitation exercises.

RESULTS

There were no significant differences between the treatment groups on outcome measures at 12 weeks and one year (see Table 10) apart from an isolated finding of greater improvement in the telephone support group on the autonomic-anxiety subscale at 12 weeks. However, Table 11 shows that the telephone support group reported spending more time on all of the rehabilitation exercises apart from the core set of basic exercises (head movements while sitting).

Table 10. Adjusted mean differences (95% CI) comparing the two intervention groups at 12 weeks and one year on all measures.

	Adjusted mean difference* (95% CI)	
	12 weeks	One year
Vertigo Symptom Score – Short Form	-1.15 (-3.12 to 0.83) P=0.253	-0.13 (-1.92 to 1.67) P=0.890
Number (%) reporting subjective improvement	Odds Ratio*=0.92 (0.53 to 1.60) P=0.771	Odds Ratio*=1.55 (0.85 to 2.81) P=0.151
Vertigo- balance subscale	-0.28 (-1.64 to 1.07) P=0.678	0.09 (-1.11 to 1.30) P=0.881
Autonomic-anxiety subscale	-0.98 (-1.90 to -0.06) P=0.037	-0.19 (-1.09 to 0.70) P=0.672
Dizziness Handicap Inventory	-0.13 (-4.26 to 4.00) P=0.949	-0.36 (-4.68 to 3.96) P=0.869
HADS Anxiety	0.26 (-0.40 to 0.93) P=0.433	-0.44 (-1.36 to 0.47) P=0.340
HADS Depression	0.26 (-0.40 to 0.93) P=0.433	-0.51 (-1.28 to 0.27) P=0.197
EQ5-D	0.004 (-0.05 to 0.05) P=0.871	0.01 (-0.03 to 0.06) P=0.557

*All analyses were adjusted for baseline levels of the stratification variable, the Vertigo Symptom Scale – Short Form, and for baseline levels of the dependent variable.

Table 11 = Comparison of intervention groups on measures of adherence.

	Booklet with telephone support (mean (SD))	Booklet self-management (mean (SD))	Mean difference (95% CI)
How many times a week on average did you carry out the therapy?	3.18 (1.12) n = 80	2.76 (1.20) n = 85	-.41 (-.77 to -.53) P=.025
How many times a day on average did you carry out the therapy?	1.39 (0.58) n = 80	1.21 (0.58) n = 86	-.18 (-.36 to -.00) P=.050
Total time spent sitting	2.58 (1.60) n = 78	2.19 (1.58) n = 85	-.39 (-.88 to .10) P=.122
Total time spent standing	2.59 (1.49) n = 79	2.10 (1.58) n = 83	-.50 (-.98 to -.02) P=.040
Total time spent walking	2.54 (1.92) n = 76	1.41 (1.68) n = 82	-1.12 (-1.69 to -.56) P=.000
Total time spent on special exercises	2.19 (2.02) n = 67	1.49 (1.84) n = 78	-.71 (-1.35 to -.07) P=.031
Total time spent on general activities	2.72 (2.11) n = 68	1.74 (1.95) n = 78	-.98 (-1.64 to -.31) P=.004