Supplementary Online Content

Traeger AC, Hübscher M, Henschke N, Moseley GL, Lee H, McAuley JH. Effect of primary care–based education on reassurance in patients with acute low back pain: systematic review and meta-analysis. *JAMA Intern Med*. Published online March 23, 2015. doi:10.1001/jamainternmed.2015.0217.

eMethods

eTable 1. Risk of Bias in Included Studies Using the PEDro Scale

eTable 2. Summary Results of Subgroup Analyses

eFigure 1. Flow Chart Indicating Selection of Studies for Inclusion

eFigure 2. Effects of Patient Education, as Compared to Usual Care/Control Education, on Components of Reassurance: Fear, Worry, Anxiety and Catastrophization

eReferences

eAppendix 1. Search Strategy for Medline (Ovid)

eAppendix 2. Content of Recommended Guideline Education and Content of Patient Education Interventions

eAppendix 3. PEDro Scale

eAppendix 4. Additional Subgroup Analysis Forest Plots (eFigures 3-6)

eAppendix 5. Funnel Plots (eFigures 7-9)

eAppendix 6. Leave-One-Out Analysis (eFigure 10)

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

© 2015 American Medical Association. All rights reserved.

eMethods

Risk of bias assessment

Two independent authors assessed individual study risk of bias using the PEDro scale.[1-3] The PEDro scale is method to assess risk of bias that has been established as valid and reliable.[1-3] The scale uses 10 dichotomous items to assess risk of bias in randomised controlled trials (see Appendix 3, eAppendix). Where available, verified PEDro scores were retrieved from the online database.[4] When PEDro scores were not available two independent assessors scored each study according to the PEDro criteria. In cases where items were not clearly reported in the manuscript, these items were determined to be not present. Studies were then categorised into high (<5/10), moderate (5-7/10) or low (>7/10) risk of bias.

Quality assessment

Two independent authors rated the overall quality of evidence for each outcome using the GRADE approach[5] recommended by The Cochrane Handbook[6] and included in the Cochrane Back Review Group method guidelines.[7] Factors that might reduce the quality of the evidence were: risk of bias in the studies, inconsistency (ie statistical heterogeneity), imprecision (ie sparse data), indirectness (ie not generalizable), and publication bias.[5] Serious limitations in one of these five domains could reduce the quality of the evidence by one level. For three key outcomes (reassurance in the short and long term, and healthcare visits at 12 months) each domain was assessed and any reasons to downgrade were given by two independent authors. Disagreements were resolved by discussion and reaching consensus.

The overall quality of evidence for each outcome was then rated as high, moderate, low or very low quality:

High quality: at least 75% of included RCTs have low risk of bias and no serious inconsistency, imprecision, indirectness or publication bias. Further research is unlikely to change estimates of effect or our confidence in results.

Moderate quality: one of the domains is not met. Further research might have important impact on our confidence in results and estimates of effect.

Low quality: two of the domains are not met. Further research is very likely to have important impact on our confidence in results and estimates of effect.

Very low quality: three of the domains are not met. We are very uncertain about our results.

Number needed to treat calculation

The number needed to treat (NNT) was estimated for healthcare utilization data to allow direct comparison to previous work in the field.[8] Given the lack of a standard measure of reassurance and to avoid uncertainty around classifying a patient as being ‘reassured’ or ‘not reassured’ we did not to calculate NNT for reassurance effect sizes. To estimate the NNT for patient education to prevent one subsequent primary care visit we performed three steps. First, we transformed the effect of patient education on healthcare use from SMD to Log Odds Ratio using the method recommended in the Cochrane Handbook. We pooled these data using a generic inverse method meta-analysis in RevMan5. Second, we estimated the ‘Patient’s Expected Event Rate’ (PEER) using control group data. PEER is the mean proportion of participants consulting primary care in the control group at 12-months. Third, we converted the pooled effect from Odds Ratio to NNT using the equation: NNT = (1-(PEER*(1-OR))) / ((1-PEER)*(PEER)*(1-OR)).[9]

© 2015 American Medical Association. All rights reserved.

eTable 1
Risk of bias in included studies using the PEDro scale

	Random allocat-ion	Conceal-ed allocation	Baseline similarity	Blind subjects	Blind therapists	Blind outcome assessors	Adequate follow-up	Intention to treat analysis	Between group comparis-ons	Point estimates and variability	Score /10
Bucker et al. 2010[10]	1[a]	1	0	0	0	0	0	0	1	1	4
Burton et al. 1999[11]	1	1	1	1	1	1	0	0	1	1	8
Cherkin et al. 1996[12]	1	0	1	0	0	1	1	0	1	1	6
Deyo et al. 1987[13]	1	0	1	0	0	1	1	1	1	0	6
Hagen et al. 2000[14]	1	1	0	0	0	0	0	1	1	1	5
Hay et al. 2005[15]	1	1	1	0	0	1	0	1	1	1	7
Hill et al. 2011[16] [b]	0	0	0	0	0	0	0	1	1	1	3
Jellema et al. 2005[17]	1	0	1	0	0	0	1	1	1	1	6
Karjalainen et al. 2003[18]	1	1	1	0	0	0	1	1	1	1	7
Leonhardt et al. 2008[19]	1	1	1	0	0	0	1	0	1	1	6
Pengel et al. 2007[20]	1	1	1	1	0	1	1	1	1	1	9
Roberts et al. 2002[21]	1	0	0	0	0	1	1	1	1	1	6
Roland and Dixon 1989[22]	0	0	0	0	0	0	1	0	1	1	3
Storheim et al. 2003[23]	1	1	1	0	0	1	0	1	1	1	7

[a] 1=criterion present; 0=criterion absent
[b] Data from this study was from a non-randomised subgroup of participants who had acute pain and received patient education only. The original RCT scored 6/10 on PEDro but was downgraded accordingly.

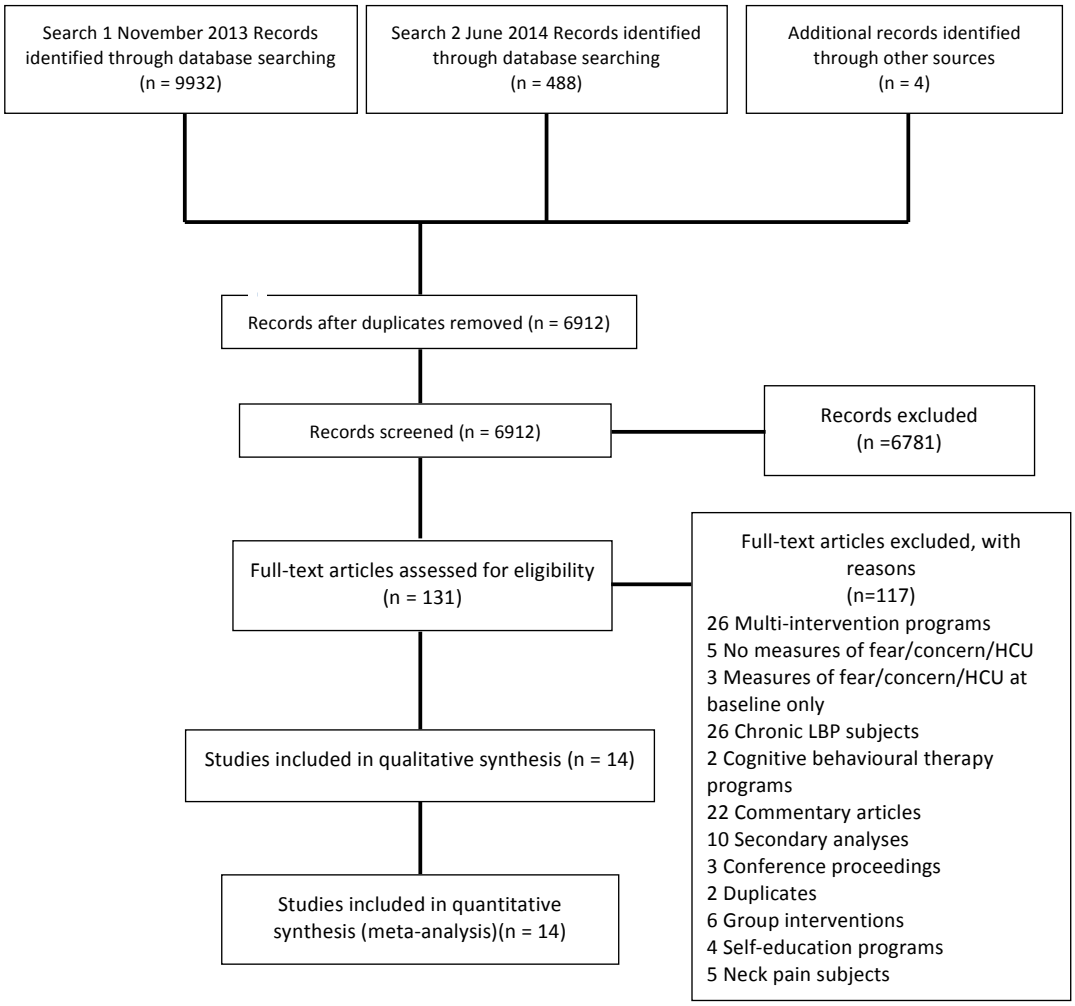
© 2015 American Medical Association. All rights reserved.

eTable 2
Summary results of subgroup analyses

Subgroup analysis variable	No of studies	Sample size		Hetero-geneity I^2 (%)	Standardised mean difference (95%CI)	Test for subgroup differences
		Education	Control			
Duration						
Very brief (<5 min)	3	235	164	72	-0.47 (-0.93 to -0.01)	
Brief (5-60min)	4	819	744	52	-0.17 (-0.34 to -0.01)	P=0.39
Long (>60min)	4	535	518	66	-0.11 (-0.33 to 0.10)	
Provider						
Physiotherapist	3	304	291	0	-0.00 (-0.15 to 0.14)	
Physician	6	649	584	69	-0.38 (-0.62 to 0.14)	P=0.03
Nurse	3	636	551	76	-0.12 (-0.40 to 0.17)	
Content						
Biopsychosocial	8	899	888	77	-0.21 (-0.41 to -0.00)	P=0.62
Biomedical	4	690	538	0	-0.27 (-0.39 to -0.15)	
Format						
Written	3	235	164	72	-0.47 (-0.93 to -0.01)	P=0.18
Verbal	9	1354	1262	61	-0.14 (-0.27 to -0.01)	

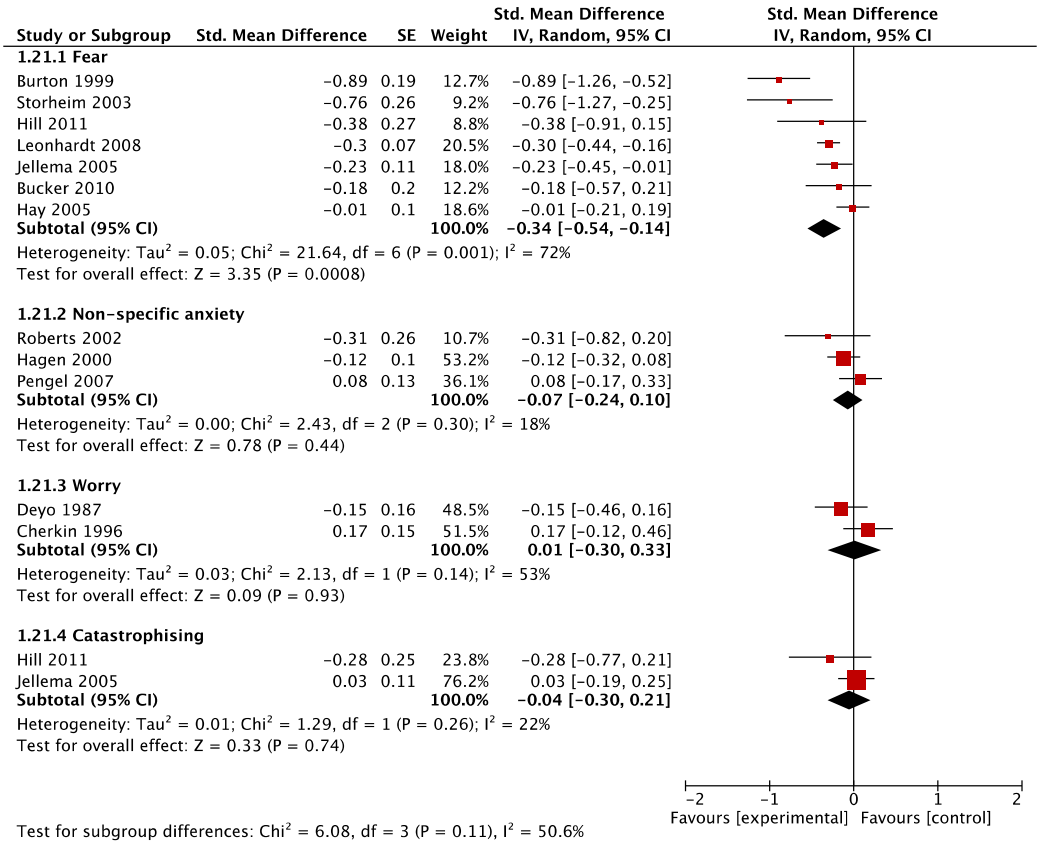
© 2015 American Medical Association. All rights reserved.

eFigure 1. Flow chart indicating selection of studies for inclusion



© 2015 American Medical Association. All rights reserved.

eFigure 2. Effects of patient education, as compared to usual care/control education, on components of reassurance: fear, worry, anxiety and catastrophization



© 2015 American Medical Association. All rights reserved.

eReferences

1. de Morton NA. The PEDro scale is a valid measure of the methodological quality of clinical trials: a demographic study. *Aust J Physiother.* 2009;55(2):129-133.
2. Macedo LG, Elkins MR, Maher CG, Moseley AM, Herbert RD, Sherrington C. There was evidence of convergent and construct validity of Physiotherapy Evidence Database quality scale for physiotherapy trials. *J Clin Epidemiol.* 2010;63(8):920-925.
3. Maher CG, Sherrington C, Herbert RD, Moseley AM, Elkins M. Reliability of the PEDro scale for rating quality of randomized controlled trials. *Phys Ther.* 2003;83(8):713-721.
4. Physiotherapy Evidence Database (PEDro). The George Institute for Global Health. http://www.pedro.org.au/. Accessed August 20, 2014.
5. Oxman AD, Group GW. Grading quality of evidence and strength of recommendations. *BMJ.* 2004;328(19):1490-1494.
6. Higgins JP, Green S. *Cochrane handbook for systematic reviews of interventions.* Vol 5: Wiley Online Library; 2008.
7. Furlan AD, Pennick V, Bombardier C, van Tulder M. 2009 updated method guidelines for systematic reviews in the Cochrane Back Review Group. *Spine (Phila Pa 1976).* 2009;34(18):1929-1941.
8. Rolfe A, Burton C. Reassurance after diagnostic testing with a low pretest probability of serious disease: systematic review and meta-analysis. *JAMA Intern Med.* 2013;173(6):407-416.

© 2015 American Medical Association. All rights reserved.

9. Centre for Evidence-Based Medicine. Number needed to treat (NNT). *Centre for Evidence-Based Medicine* 2012; http://www.cebm.net/number-needed-to-treat-nnt. Accessed July 2014.

10. Bücker B BM, Isfort J, Koneczny N, Vollmar HC, Lange S, Lutz G, Rieger MA, . Effect of written patient information on knowledge and function of patients with acute uncomplicated back pain (PIK Study). *Gesundheitswesen.* 2010;72(12):e78-88.

11. Burton AK, Waddell G, Tillotson KM, Summerton N. Information and advice to patients with back pain can have a positive effect. A randomized controlled trial of a novel educational booklet in primary care. *Spine (Phila Pa 1976).* 1999;24(23):2484-2491.

12. Cherkin DC, Deyo RA, Street JH, Hunt M, Barlow W. Pitfalls of patient education: limited success of a program for back pain in primary care. *Spine (Phila Pa 1976).* 1996;21(3):345-355.

13. Deyo RA, Diehl AK, Rosenthal M. Reducing roentgenography use. Can patient expectations be altered? *Arch Intern Med.* 1987;147(1):141-145.

14. Hagen EM, Eriksen HR, Ursin H. Does early intervention with a light mobilization program reduce long-term sick leave for low back pain? *Spine (Phila Pa 1976).* 2000;25(15):1973-1976.

15. Hay EM, Mullis R, Lewis M, et al. Comparison of physical treatments versus a brief pain-management programme for back pain in primary care: a randomised clinical trial in physiotherapy practice. *Lancet.* 2005;365(9476):2024-2030.

© 2015 American Medical Association. All rights reserved.

16. Hill JC, Whitehurst DG, Lewis M, et al. Comparison of stratified primary care management for low back pain with current best practice (STarT Back): a randomised controlled trial. *Lancet.* 2011;378(9802):1560-1571.

17. Jellema P, Windt DA, Horst HE, Twisk JW, Stalman WA, Bouter LM. Should treatment of (sub)acute low back pain be aimed at psychosocial prognostic factors? Cluster randomised clinical trial in general practice. *BMJ.* 2005;331(7508):84.

18. Karjalainen K, Malmivaara A, Pohjolainen T, et al. Mini-intervention for subacute low back pain: a randomized controlled trial. *Spine (Phila Pa 1976).* 2003;28(6):533-540.

19. Leonhardt C, Keller S, Chenot JF, et al. TTM-based motivational counselling does not increase physical activity of low back pain patients in a primary care setting-A cluster-randomized controlled trial. *Patient Educ Couns.* 2008;70(1):50-60.

20. Pengel LH, Refshauge KM, Maher CG, Nicholas MK, Herbert RD, McNair P. Physiotherapist-directed exercise, advice, or both for subacute low back pain: a randomized trial. *Ann Intern Med.* 2007;146(11):787-796.

21. Roberts L, Little P, Chapman J, Cantrell T, Pickering R, Langridge J. The back home trial: general practitioner-supported leaflets may change back pain behavior. *Spine (Phila Pa 1976).* 2002;27(17):1821-1828.

22. Roland M, Dixon M. Randomized controlled trial of an educational booklet for patients presenting with back pain in general practice. *J R Coll Gen Pract.* 1989;39(323):244-246.

© 2015 American Medical Association. All rights reserved.

23. Storheim K, Brox JI, Holm I, Koller AK, Bø K. Intensive group training versus cognitive intervention in sub-acute low back pain: short-term results of a single-blind randomized controlled trial. *J Rehabil Med.* 2003;35(3):132-140.

© 2015 American Medical Association. All rights reserved.

eAppendix 1. Search strategy for Medline (Ovid)

1	randomized controlled trial.pt.
2	controlled clinical trial.pt.
3	comparative study.pt.
4	clinical trial.pt.
5	randomized.ab.
6	placebo.ab,ti.
7	drug therapy.fs.
8	randomly.ab,ti.
9	trial.ab,ti.
10	groups.ab,ti.
11	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
12	(animals not (humans and animals)).sh.
13	11 not 12
14	dorsalgia.ti,ab.
15	exp Back Pain/
16	backache.ti,ab.
17	exp Low Back Pain/
18	(lumbar adj pain).ti,ab.
19	coccyx.ti,ab.
20	coccydynia.ti,ab.
21	sciatica.ti,ab.
22	sciatic neuropathy/
23	spondylosis.ti,ab.
24	lumbago.ti,ab.
25	back disorder$.ti,ab.
26	14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25
27	13 and 26
28	Neck Muscles/
29	exp Neck/
30	exp Neck Pain/
31	Whiplash Injuries/
32	neck.ti,ab.
33	28 or 29 or 30 or 31 or 32
34	13 and 33
35	27 or 34
36	Patient Education as Topic/
37	Patient-Centered Care/
38	Education/
39	"Early Intervention (Education)"/
40	psychoeducation.ti,ab.
41	education$.ti,ab.
42	reassur$.ti,ab.
43	(advice or advise).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
44	information booklet.ti,ab.
45	book$.ti,ab.
46	pamphlet$.ti,ab.
47	leaflet$.ti,ab.
48	exp Consumer Health Information/
49	consultation.ti,ab.
50	36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49
51	35 and 50

eAppendix 2. Content of recommended guideline education and content of patient education interventions

Table A
Content of patient education recommended by clinical guidelines

	Provide information on cause	**Reassur-ance**	**Advice to stay active**	**Good prognosis**	**Return to work asap**	**Return to usual activity**	Analgesia	Psych factors	Strength of spine	Mechanics/ ergonomics	**Self-manage-ment**	Hurt doesn't equal harm	Anatomy	Lifting advice
Australia	**x**	**x**	**x**	**x**										
Austria				**x**		**x**								
Canada		**x**			**x**	**x**								
Europe		**x**	**x**		**x**	**x**								
Finland				**x**		**x**					x			
France														
Germany						**x**	x							
Italy	**x**	**x**	**x**	**x**	**x**	**x**		x	x					
New Zealand		**x**	**x**											
Norway			**x**		**x**	**x**								
Spain		**x**	**x**											
The Netherlands			**x**			**x**								
UK	**x**	**x**	**x**	**x**						x	x	x		avoid
US	**x**		**x**	**x**									x	

Table B
Content of patient education delivered in trials included in this review

	Provide information on cause	**Reassur-ance**	**Advice to stay active**	**Good prognosis**	**Return to work**	**Return to usual activity**	Analgesia	Psych factors	Strength of spine	Mechanics/ ergo-nomics	**Self manage-ment**	Hurt doesn't equal harm	Anatomy	Lifting advice
Bucker et al. 2010	x	x	x											
Burton et al. 1999*	x	x	x	x	x	x	?	x	x	x	x	x		
Cherkin et al. 1996*	x	x	x	x		x					x	x		
Deyo et al. 1987	x	x											x	
Hay et al. 2005*	x	x	x			x		x			x	x		
Jellema et al. 2005*	x	x	x	x	x	x		x	x	x	x	x		
Karjalainen et al. 2003*	x	x	x	x		x	x		x	x			x	x
Leonhardt et al. 2008			x											
Pengel et al. 2007	x	x	x	x	x	x		x	x		x	x		
Roberts et al. 2002	x		x	x						x	x		x	x
Roland and Dixon 1989										x			x	x
Storheim et al. 2003*	x	x	x	x						x	x		x	x
Hagen et al. 2000*	x	x	x	x	x	x		x	x	x	x	x	x	
Hill et al. 2011*	x	x	x	x	x	x	x	x			x			

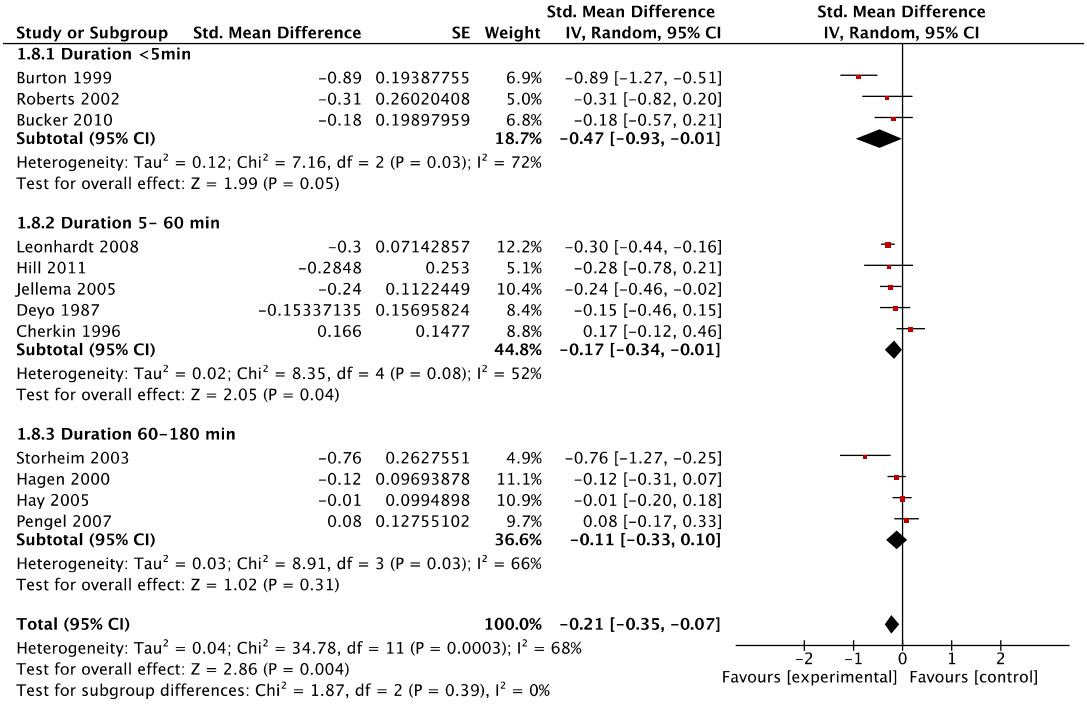
* Intervention classified as 'biopsychosocial' content to allow subgrouping. Biopsychosocial content included discussion of psychosocial factors and covered topics that are common to international clinical guidelines

eAppendix 3. PEDro scale

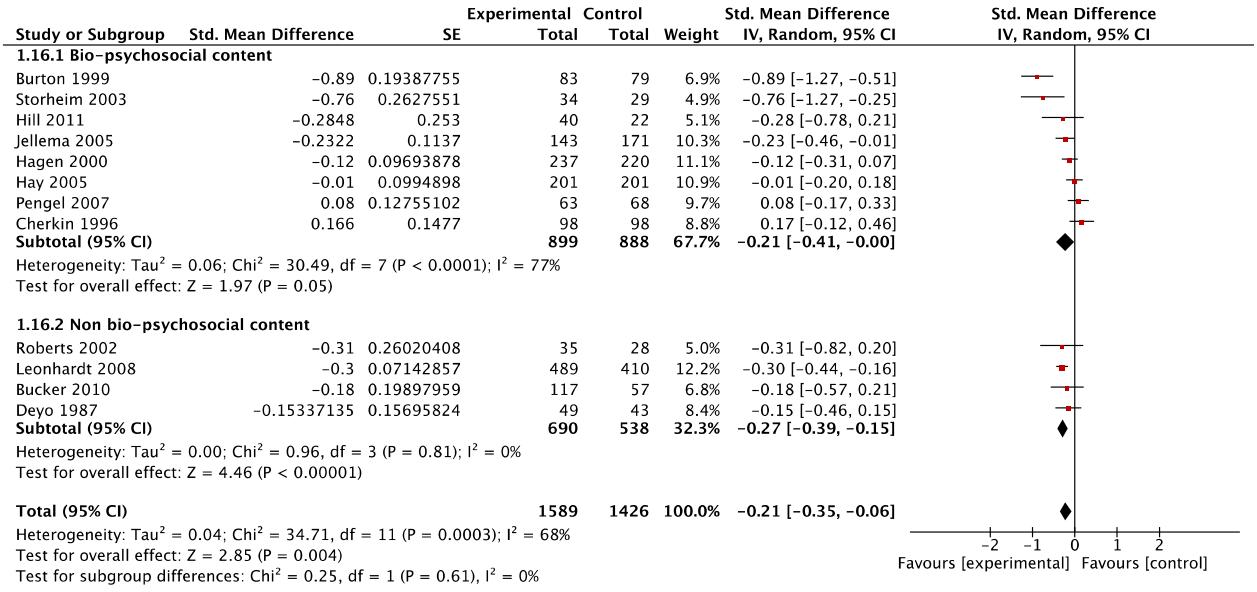
Table C Description of PEDro items	
Random allocation	subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)
Concealed allocation	allocation was concealed
Baseline similarity	the groups were similar at baseline regarding the most important prognostic indicators
Blind therapists	there was blinding of all subjects
Blind patients	there was blinding of all therapists who administered the therapy
Blind outcome assessors	there was blinding of all assessors who measured at least one key outcome
Adequate follow-up	measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups
Intention to treat analysis	all subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”
Between group comparisons	the results of between-group statistical comparisons are reported for at least one key outcome
Point estimates and variability	the study provides both point measures and measures of variability for at least one key outcome

eAppendix 4: Additional Forest Plots (eFigures 3-6)

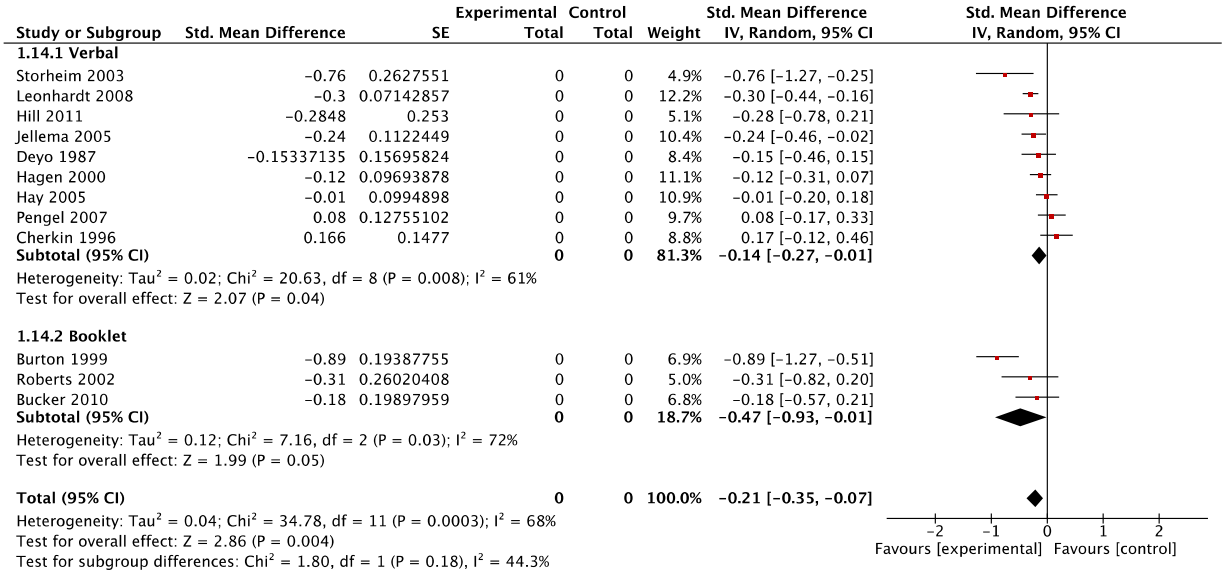
eFigure 3 Differences in short term effects on reassurance when patient education interventions are stratified according to the duration of the intervention.



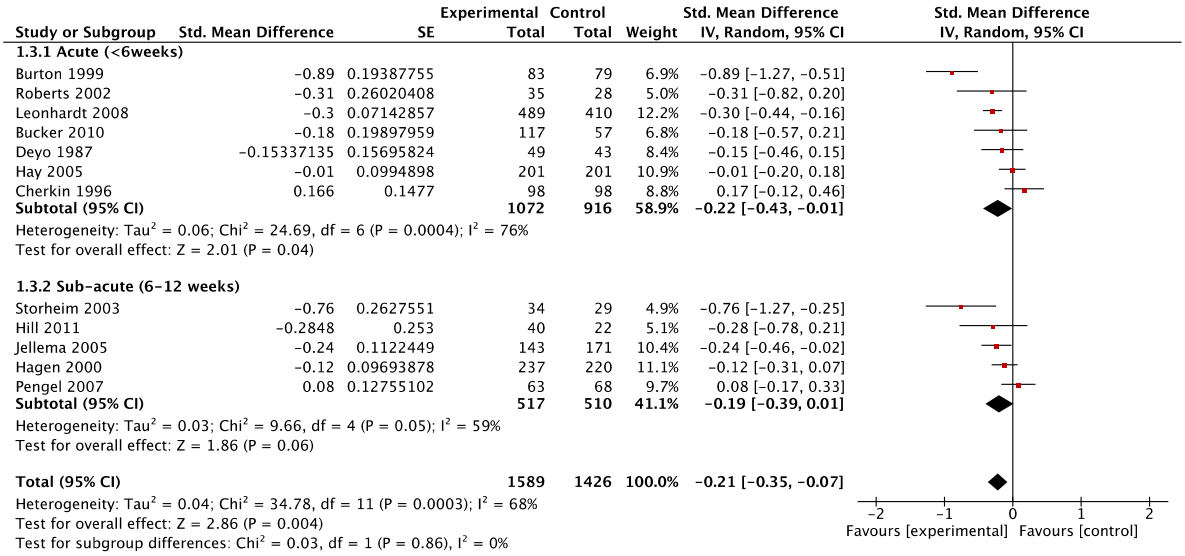
eFigure 4. Differences in short term effects on reassurance when patient education interventions are stratified according to the content of the intervention.



eFigure 5. Differences in short term effects on reassurance when patient education interventions are stratified according to the format of the intervention.

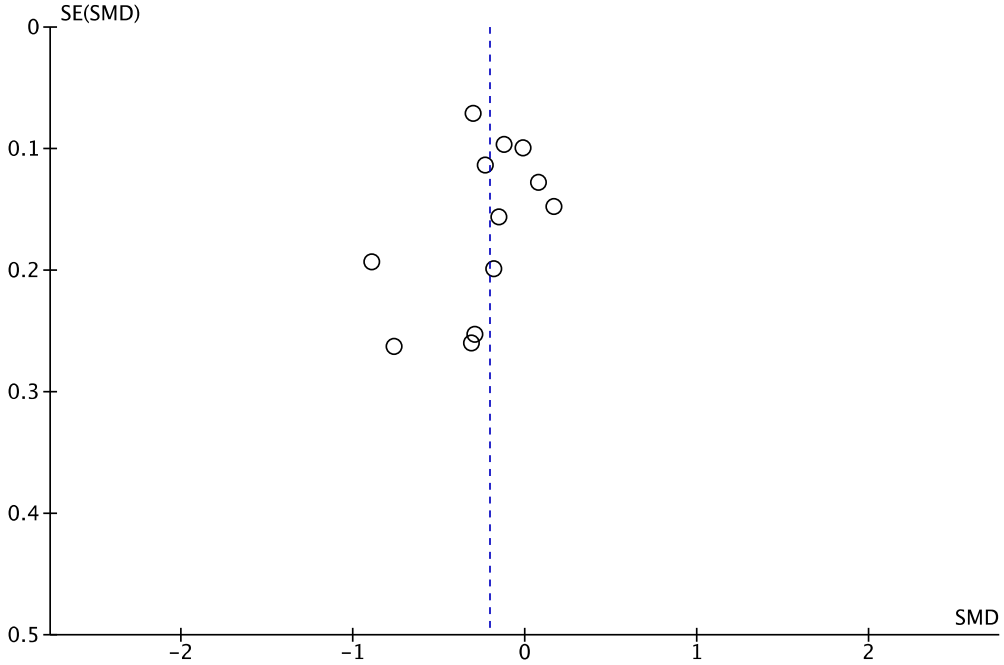


eFigure 6. Differences in short term effects on reassurance when patient education interventions are stratified according to duration of symptoms.

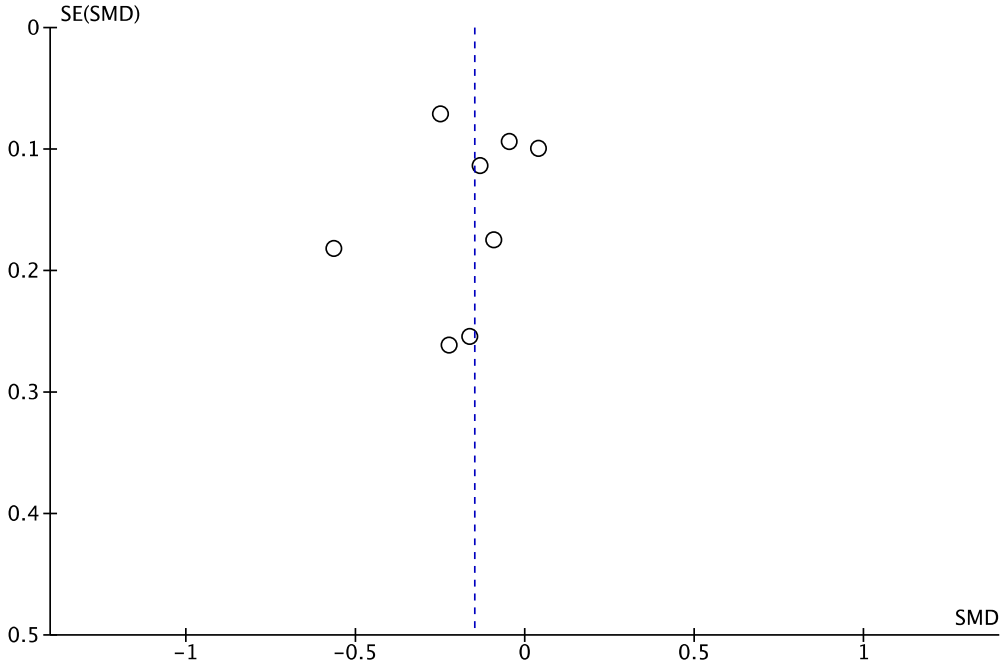


eAppendix 5: Funnel Plots (eFigures 7-9)

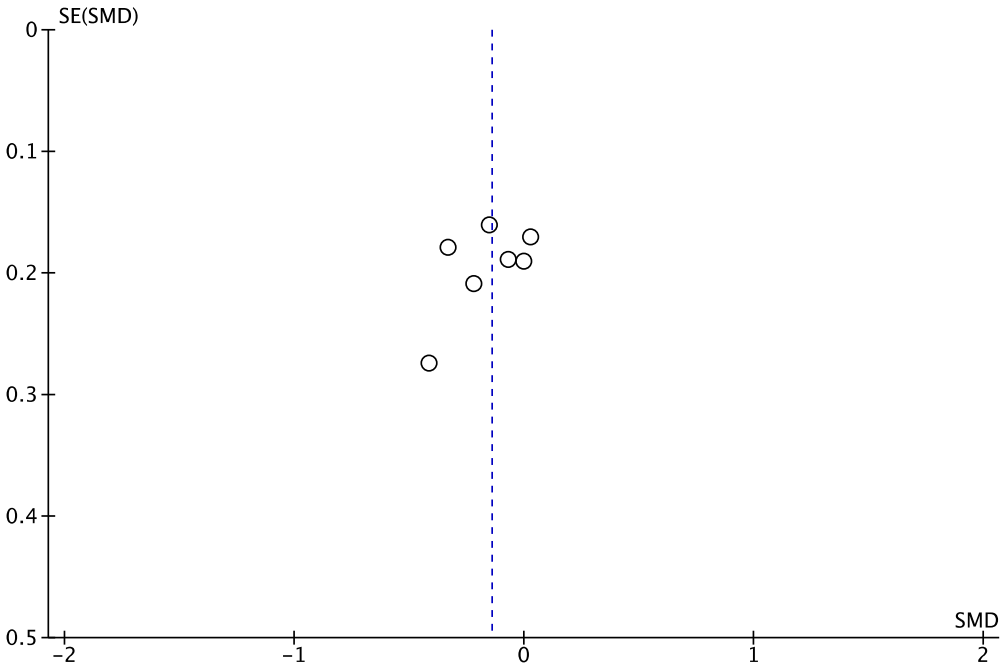
eFigure 7. Funnel plot for primary outcome 1: Short term reassurance



eFigure 8. Funnel plot for primary outcome 2: Long term reassurance

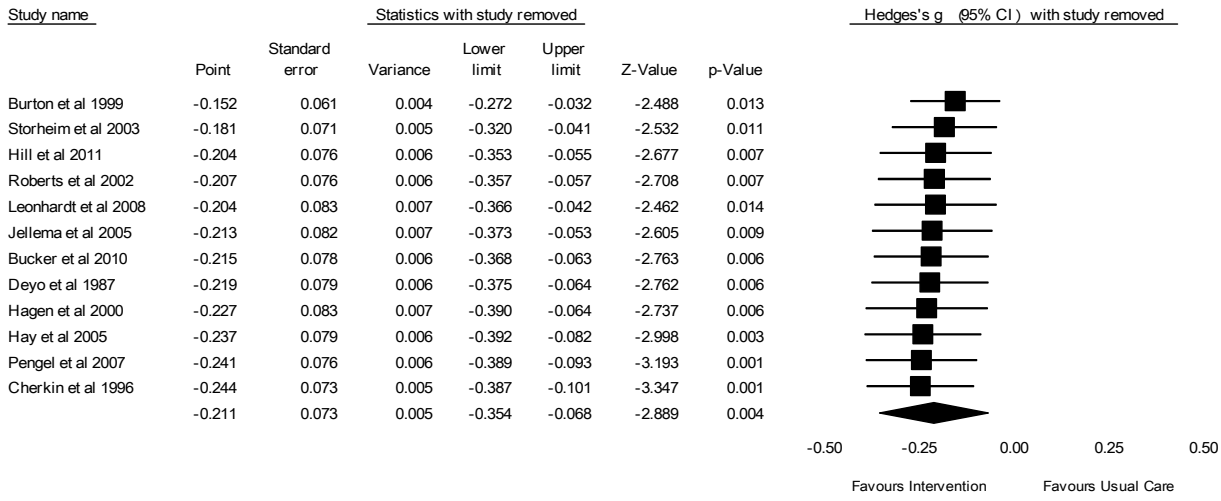


eFigure 9. Funnel plot for primary outcome 3: Healthcare utilization



eAppendix 6: Leave-One-Out Analysis (eFigure 10)

eFigure 10. Study influence plot: effect size estimates when one study is removed



Study name	Point	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
Burton et al 1999	-0.152	0.061	0.004	-0.272	-0.032	-2.488	0.013
Storheim et al 2003	-0.181	0.071	0.005	-0.320	-0.041	-2.532	0.011
Hill et al 2011	-0.204	0.076	0.006	-0.353	-0.055	-2.677	0.007
Roberts et al 2002	-0.207	0.076	0.006	-0.357	-0.057	-2.708	0.007
Leonhardt et al 2008	-0.204	0.083	0.007	-0.366	-0.042	-2.462	0.014
Jellema et al 2005	-0.213	0.082	0.007	-0.373	-0.053	-2.605	0.009
Bucker et al 2010	-0.215	0.078	0.006	-0.368	-0.063	-2.763	0.006
Deyo et al 1987	-0.219	0.079	0.006	-0.375	-0.064	-2.762	0.006
Hagen et al 2000	-0.227	0.083	0.007	-0.390	-0.064	-2.737	0.006
Hay et al 2005	-0.237	0.079	0.006	-0.392	-0.082	-2.998	0.003
Pengel et al 2007	-0.241	0.076	0.006	-0.389	-0.093	-3.193	0.001
Cherkin et al 1996	-0.244	0.073	0.005	-0.387	-0.101	-3.347	0.001
	-0.211	0.073	0.005	-0.354	-0.068	-2.889	0.004