Additional file 4. Patient related outcome measures

ТҮРЕ	DOMAIN	INSTRUMENT	DATA COLLECTION TIME POINTS
Primary	Back-related functional impairment	Roland Morris Disability Questionnaire [1]	0, 2w, 6w, 3m, 6m
		24-item scale. Each item score yes or no, high scores indicate severe impairment	
Secondary	Pain	Numeric Pain Rating Scales	0, 2w, 6w, 3m, 6m
		How bad has your back pain been in the last 24 hours?	
		How bad has your leg pain been in the last 24 hours?	
		Eleven-point numeric rating scales where 0 = no pain, 5 = moderate pain, and 10 = worst possible pain	
	Activity limitation	Numeric Disability Rating Scale	0, 2w, 6w, 3m, 6m
		How much has your back pain limited your daily activities in the last 24 hours?	
		Eleven-point numeric rating scales where 0 = no limitation, 5 = moderate limitation, and 10 = unable to carry out any activities at all	
	Health related quality of life	EuroQol-5D [2]	0, 3m, 6m
		Five-item scale with three response options: no problem, moderate problems, severe problems	
	Satisfaction	With information received	0, 2w, 0, 2w, 6w, 6m
		How satisfied are you with the information you received about your back pain?	
		Where 0 = very dissatisfied and 6 = very satisfied	
		With care received [3] modified by [4]	
		How satisfied are you with the treatment you received for your back pain?	
		Where 0 = very dissatisfied and 6 = very satisfied	
		Rating of the overall results of care [3]	2w, 6w, 6m
		If you had to spend the rest of your life with the symptoms you have right now, how would you feel about it?	
		Where 0 = very dissatisfied and 6 = very satisfied	
	Economic consequences	Modified Otago Costs and Consequences Questionnaire for Low Back Pain [5] includes:	2w, 3m, 6m
		 Work loss due back problem Medications consumption Healthcare consumption Carer / support person time 	
		Out-of-pocket expenses	

1

From: Darlow B, Stanley J, Dean S, Abbott JH, Garrett S, Mathieson F, Dowell A (2017). The Fear Reduction Exercised Early (FREE) approach to low back pain: protocol for a cluster randomised, parallel-group, superiority trial of patient impairment 6-months post general practitioner consultation.

ТҮРЕ	DOMAIN	INSTRUMENT	DATA COLLECTION TIME POINTS
		ACC claim cost	6m
Process	Pain self-efficacy	PSEQ-2 [6]	0, 2w, 6w,
		Please rate how confident you are that you can do the following things at present, despite the pain	
		I can do some form of work, despite the pain ("work" includes housework and paid and unpaid work).	
		I can live a normal lifestyle, despite the pain	
		where 0 = not at all confident and 6 = completely confident	
	Expectation	I think I will be able to do my regular job, without any restrictions, 4 weeks from now [7]	0, 2w, 6w
		I think I will be able to do my regular job, without any restrictions, 3 months from now [8]	
		Where 0 = Unlikely and 6 = Definitely	
	Fear avoidance	Physical activity might harm my back I should not do physical activities which (might) make my pain worse [9, 10]	0, 2w, 6w
		0 = Completely disagree and 6 = Completely agree	
	Anxiety	I feel anxious or worried about my back[10]	0, 2w, 6w
		0 = Not at all and 6 = Quite anxious	
	Catastrophisation	I feel that my back pain is terrible and it's never going to get any better [11]	0, 2w, 6w
		Where 0 = Not at all and 6 = All the time	

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