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Original Article

Home-based pre-surgical psychological intervention for knee osteoarthritis (HAPPiKNEES): A feasibility randomised controlled trial

Introduction

Total knee arthroplasty is an effective procedure for the management of chronic pain in late stage knee osteoarthritis.[1, 2] However, up to 20% continue to suffer pain, disability and distress *after* surgery. Given that in 2016 there were over 100,000 knee replacement procedures conducted in the UK (the majority of which were total knee replacements; ref), with each procedure costing in excess of £7,000 (ref) and number of people likely to need such procedures projected to rise (ref), the 20% who continue to suffer despite surgery represents a substantial personal and economic burden. Preoperative pain and worse mental health scores are predictive of worse postoperative pain outcomes.[3] In particular, preoperative depression and anxiety were associated with high pain levels one to two years after total knee arthroplasty.[4, 5] Preoperative depression is also strongly associated with preoperative pain severity.[6] Psychological distress has negative effects on functional outcomes and imposes role limitations in older patients after total knee arthroplasty.[7]

This evidence suggests that a reduction in anxiety and depression preoperatively may lead to improved postoperative outcomes. Previous studies have used 'information giving' preoperative classes[8-10] to address emotional problems, but have not specifically targeted the reduction of anxiety and depression. Cognitive behavioural therapy is an

effective psychological treatment for depression and anxiety and is considered to be a treatment of choice for people with these conditions.[11] However, there is limited research evaluating the clinical and cost-effectiveness of *preoperative* cognitive behavioural therapy based intervention to improve *postoperative* total knee arthroplasty outcomes.[12,13]

Our aim was to determine the feasibility of conducting a randomised controlled trial to investigate the clinical and cost-effectiveness of home-administered pre-surgical psychological intervention (based on cognitive behavioural therapy) alongside usual care versus usual care alone for people on a waiting list for total knee arthroplasty for knee osteoarthritis. Specifically, we wanted to: (1) assess the feasibility of recruitment and assessment procedures; (2) evaluate the acceptability of the treatment protocol and feasibility of delivering the intervention, and assessments; (3) identify parameter estimates for a definitive trial; (4) gather detailed qualitative feedback on the intervention and study procedures.

Methods

A more extensive description of the methodology is published in the study protocol.[14] In brief, this was a multi-centre, mixed-methods feasibility randomized controlled trial of a brief psychological intervention, based on cognitive behavioural therapy, plus usual care versus usual care-only control for people with knee osteoarthritis. Ethical approval was obtained from the National Research Ethics Service Committee – Nottingham 1 (reference 14/EM/0099), and the trial was prospectively registered (ISRCTN80222865).

Participants were recruited from knee surgery pathways at two United Kingdom National Health Service (NHS) hospitals. Patients attending clinic appointments were

invited to complete the Hospital Anxiety and Depression Scale.[15] Also, the orthopaedic clinical team identified potential participants from their databases and sent them an invitation letter and the Hospital Anxiety and Depression Scale.

Patients were included if they were over 18y, listed for total knee arthroplasty, had osteoarthritis of the knee (defined using European League Against Rheumatism criteria),[16] and had anxiety or depression (defined as a score of >7 on either Hospital Anxiety and Depression Scale subscale).[17] Patients were excluded if they had co-morbid severe psychiatric conditions, had inflammatory arthritis or were currently receiving any psychological interventions.

Eligible participants who provided written consent completed baseline assessments. These included the Western Ontario and McMaster Universities Osteoarthritis Index,[18] Intermittent and Constant Osteoarthritis Pain scale,[19] Beck Depression Inventory,[20] Beck Anxiety Inventory,[21] EQ-5D-5L,[22, 23] and a bespoke service-use questionnaire to assess use of NHS and social services (see online *Supplementary Document 1*).

Participants were then randomly allocated to either psychological intervention plus usual care (intervention) or usual care-only (control) on a 1:1 ratio, using a computer-generated random code, by an independent researcher not involved with the study. The recruiting researcher telephoned the independent researcher and provided the initials and date of birth of the participant, which was recorded before the allocation was revealed. The researchers and trial statistician remained blind to group allocation

throughout the study. Recruitment continued until 50 participants had been randomised. This sample size was sufficient to inform the design of a phase III trial.[24]

Participants allocated to the intervention arm could receive *up to* ten sessions of psychological intervention, based on general principles of cognitive behavioural therapy for anxiety, depression and pain management, tailored to the needs of each participant. The intervention combined the core elements of cognitive behavioural therapy for pain management outlined by Gatchel et al.,[25] Morley,[26] and the Gloucester Pain Management Manual.[27] Contents included: psychoeducation on the relationship between mood and pain; values-based goal-setting; self-management and behavioural activation; relaxation and mindful breathing; cognitive restructuring; and post-surgical planning (copies of the treatment manual are available from the authors). The hour-long sessions, scheduled to fit within the expected waiting time for surgery (maximum 18 weeks), were held once or twice weekly. One of two psychologists, trained in delivering cognitive behavioural therapy based interventions, offered the intervention in participants' homes or at a hospital, as preferred by the participant. To assess fidelity, therapy sessions were audio-recorded with participants' consent.

Participants allocated to usual care did not receive any therapeutic input from the psychologists, but received the standard care delivered by each clinical service. Standard care received by the control group did not include any specific focus on patient's psychological state. All other clinical services were provided as usual for both groups.

Participants from both groups were assessed four and six months after randomisation using the same assessments used at baseline. The outcome measures were

posted to the participants with a pre-paid return envelope. Participants received assistance by telephone from a researcher if they had difficulty completing the questionnaires.

Brief semi-structured feedback interviews were conducted between follow-ups, with purposefully selected participants from the intervention (n=11) and usual care groups (n=12) to assess acceptability, barriers, and facilitators of the intervention and the study procedures. A maximum variation sampling strategy was used to achieve a heterogeneous sample.[28]

Treatment was coded as 'completed' if it was terminated by the therapist in consultation with the participant after all the key issues (goals) had been dealt with, or `discontinued' if it was terminated by participants without consultation with the therapist. Descriptive statistics were used to describe the sample, indicate retention rates and to inform power and sample size calculations for a definitive study. T-tests and Mann-Whitney U-tests (for parametric and non-parametric data, respectively) were used to compare the intervention and control groups on pain and mood outcomes. Rasch converted scores were also used, where available.[29] Analyses were conducted on an intention-to-treat basis.

Qualitative data were analysed using a framework approach,[30-32] which is a hierarchical, matrix-based analysis method, particularly suited where the research goals are clearly defined at the onset (e.g., to support the development of a future definitive trial).

Results

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Fifty-one participants were randomised, 48 from one site and 3 from the other (please see the CONSORT diagram [Figure 1]). Demographic characteristics are shown in Table 1. The groups were well-matched on demographic and surgery characteristics at baseline. The mean anxiety and depression subscale scores *for both* were in the 'mild' range (i.e., total subscale score between 8 and 10). However, using the cut-off suggested by Axford et al.[17] , based on available Hospital Anxiety and Depression Scale screening data from 102 participants, 38 (37%) and 31 (30%) of those screened were not in the 'normal' range for depression and anxiety, respectively. Most scored in the 'moderate' range for depression (n=20, 19.6%) and 'mild' range for anxiety (n=15, 14.7%). Only a small proportion presented with 'severe' depression or anxiety (n=5 [4.9%] and n=3 [2.9%], respectively).

Figure 1

Table 1

Of the 222 participants screened, 51 (23%) were randomised. One participant was excluded after randomisation, due to a miscalculation of the Hospital Anxiety and Depression Scale baseline score to ascertain eligibility. Their data were excluded from the analyses.

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At 4-month follow-up, 48 outcome questionnaires were posted (2 participants had withdrawn), and 30 (60%) were returned. Ten were returned with no telephone support to complete the questionnaires. At 6-month follow-up, 25 (50%) of the questionnaires were returned; 19 did not require telephone support (Figure 1).

Table 2 shows the amount of missing data, and the success of obtaining these data by telephone, per scale and by data collection point. The data from the service-use questionnaire are not included here as some questions would have not been relevant for some participants and there was no 'not applicable category', so we were unable to tell if the data were missing or not applicable. Overall, less than 9% of data were missing at the three data collection points.

Two participants had omitted the pages containing the Western Ontario and McMaster Universities Osteoarthritis Index items in the questionnaire booklet (120 missing items). One participant at 4-month and one participant at 6-month follow-up retuned an empty questionnaire booklet. Most commonly missed Western Ontario and McMaster Universities Osteoarthritis Index items were those that related to use of stairs (items 2, 8, and 9), or a bath (item 20). Some participants wrote 'no stairs' or 'no bath' beside these questions. Other questions commonly missed were question 5 (pain standing upright), 13b (pain walking on a flat surface), 22 (pain getting on or off the toilet), and 23 (pain performing heavy domestic duties).

Table 2

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Outcome effect sizes ranged from small (d=0.005) to moderate (d=0.74) (Table 3). Western Ontario and McMaster Universities Osteoarthritis Index physical function scores were significantly higher in the intervention than in the usual care group 6 months after randomisation (d=1.16).

Table 3

Of the 50 patients in the study only 21 completed the EQ-5D™ at all time points – complete cases. Numerically, the mean utility and VAS scores of the patients who failed to complete follow-ups 1 (T1) and 2 (T2) were lower than the complete cases, but there was considerable heterogeneity. The use of NHS resources was, in the main, equal amongst control and intervention groups pre-baseline, but differed between the groups at follow-ups 1 and 2. Given the feasibility nature of the trial and the small number of complete cases no statistical testing was undertaken.

Participants received 2 to 8 sessions of psychological intervention (mode=3 sessions). Of the 25 participants who were allocated to the treatment group, two participants withdrew. One did not want to engage with any services not directly related to their surgical care. The other did not feel they would benefit from the treatment.

In total, ten participants discontinued treatment. Three discontinued after one session, because they felt they were coping well. Seven discontinued treatment after receiving more than one session, of which one participant discontinued treatment after

eight sessions because they were not able to discuss the main cause of their anxiety. Seven participants did not complete treatment due to surgery being brought forward. The mean number of days between recruitment and surgery was 101.18 days (SD=58.11; range 4-277 days). Six participants completed treatment as planned. Seventeen of the 23 participants who received the intervention consented to having their therapy sessions audio-recorded.

The overall intervention costs comprised the total staff time required to deliver the intervention, plus any travel costs incurred. The sessions were carried out by NHS Agenda for Change band 6 and 8a psychologists. The hourly pay rates range from £98 to £138 (based on 2014 PSSRU, ref). The costs per patient for the intervention varied according to whether they were delivered by the Grade 6 or 8a psychologist and the time in each session. Total intervention costs (including staff time for therapy and travel and mileage costs) ranged from Grade 6 £10,148.64 to Grade 8a £15,028.24 (further data can be found in Supplementary Document).

To determine the sample size for the full trial, we considered pain and mood outcomes as potential primary outcomes i.e. Western Ontario and McMaster Universities Osteoarthritis Index, Intermittent and Constant Osteoarthritis Pain scale, Beck Depression Inventory and Beck Anxiety Inventory. Table 4 shows sample size estimates for each of these measures.

Table 4

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Framework analysis of the qualitative data highlighted three main themes, which are presented below (see online *Supplementary Document* 2 which includes a description of each theme and illustrative quotes).

The first theme encompassed participants' experiences of being in the study. Overall, a majority of participants found the rationale of the study and the information provided clear. Some participants reported that they could not remember the finer details of the recruitment process due to the busy nature of the clinics, and feeling 'overwhelmed' soon after being informed that they would be receiving surgery. Most control participants understood the rationale of randomisation and did not mind not receiving the treatment. However, some control participants did not clearly understand the need for a control group.

The second theme encompassed participants' views on the outcome measures. Participants felt the focus of the measures was good and comprehensive, asking the 'right' kind of questions. Some participants did not understand the connection between total knee arthroplasty and some of the questions on the generic mood and quality of life questionnaires. Furthermore, some participants objected to answering some mood questionnaire items, and some found the service-use questionnaire difficult to complete. Half felt there were too many questionnaires. Although many participants were positive about the ease of completion, some participants thought some questions were contradictory or repetitive, which made them feel they had to check they were being consistent. Some participants also felt the timing of the outcomes was not right, because they were still in the recovery period from the surgery at 4 months post-randomisation.

Finally, the third theme encompassed the treatment experiences of the participants from the intervention group. There was a generally positive assessment of the intervention, with participants expressing an understanding of the thoughts-mood-pain interaction, and its relation to total knee arthroplasty. There were some initial concerns about what benefit it might offer, and in a few cases these doubts were never lost. For these participants, pain was physical and could only be managed by medication or physiotherapy. There were some participants who did not agree with the thoughts-mood-pain interaction, and reported that the efficacy of changing one's thoughts to manage pain went only as far as the severity of pain that one was experiencing. Benefits of the intervention were described in terms of reassurance, relaxation, calmness, positive thoughts, thinking differently, and having more realistic expectations. Some participants perceived no benefit of cognitive behavioural therapy.

Where benefits of the intervention were reported, participants attributed these to the relaxation exercises, specific techniques learnt (e.g., distraction, challenging negative assessments), 'personalising' the therapy to their individual circumstances, psychoeducation, and signposting to relevant services. The reassurance of an expert voice was mentioned on several occasions, and equally was the notion that the therapists were 'nice'.

Discussion

We demonstrate that despite some of the shortcoming of the present study, on balance, it is feasible to conduct a definitive randomised controlled trial to evaluate the clinical and cost-effectiveness of pre-surgical psychological intervention for those listed for total knee

arthroplasty for knee osteoarthritis. To ensure the success of a phase III randomised controlled trial, some of the learning points gained from this study need to be carefully considered. Therefore, in this discussion we outline the successes and the challenges we faced, and offer suggestions as to how to overcome these challenges.

We were able to recruit our target number of participants within the expected timeframe, but mainly from one centre. In this centre, there was a combination of clinical staff who were committed to the research project and a team of research nurses who were available to recruit participants within the clinic. Therefore, a Phase III trial will need research nurses whose main role would be to recruit participants and conduct baseline assessments. The qualitative data suggested that clinic recruitment was successful but some participants felt 'overwhelmed' by the trial information. While most participants understood the rationale for randomisation and the need for control groups, some did not. Other studies have also demonstrated this issue.[33, 34] Therefore, more work is needed in educating the participants about trial procedures before they are consented. Providing additional written materials (including audio-visual/multimedia presentations), additional informed consent discussions, and test/feedback techniques have shown to improve patient comprehension of study procedures.[35]

Participants received 2 to 8 sessions of psychological intervention within the period of being listed for total knee arthroplasty and the surgery. Not everyone who started treatment completed the intervention as planned. Indeed, of the 23 who began treatment, only six completed treatment. Discontinuation was due to surgery being moved forward for about a quarter of the participants, or due to personal or other reasons.

The qualitative data suggested that most, but not everyone, understood the rationale of the thoughts-mood-pain interaction. This was also informally reported to the study team by the treating therapists. This may explain why some participants withdrew from the trial or discontinued treatment. The qualitative data also highlighted that therapist factors (e.g., manner, skill) might serve as a motivating factor for participants to continue with treatment. The intervention, therefore, may need to be limited to 3-4 sessions, with the therapist identifying a few key aspects to address in the sessions, to ensure that the intervention is completed before surgery.

Once randomised, the retention rate was adequate. Two withdrew soon after randomisation, eight withdrew at the 4-month outcomes, and a further four at the 6-month outcome. Thirty participants (60%) completed the outcome measures at 4 months. At the 4-month follow-up, more people in the intervention than control group completed the outcome measures on time (i.e., within two weeks of posting the outcome questionnaires), but at the 6-month follow-up, the response rate was comparable. However, at 6 months, only 25 participants (50%) completed the outcome measures. At 4-months 10 participants (20.8%) returned the questionnaires without telephone support to complete them, compared to 19 participants (47.5%) at 6-months. Missing items were successfully collected over the telephone. We therefore feel that support to complete questionnaires over the phone is needed, which may also improve response rates.

A key finding is that the outcome measures are consistent with clinically important benefit despite the limitations of the study. The assessment of pain, using the Western Ontario and McMaster Universities Osteoarthritis Index and the Intermittent and

Constant Osteoarthritis Pain scale, was a suitable outcome. Although the Western Ontario and McMaster Universities Osteoarthritis Index physical function scores were significantly higher in the intervention than in the usual care group 6 months after randomisation, this is likely to be a chance finding, due to multiple comparisons. Reflecting on what can be done to improve outcome completion rates, this may be improved by using only one pain measure rather than two. This is consistent with participant feedback about the outcome measures being too many and too repetitive. We also feel that rather than using two mood measures (Beck Depression Inventory and Beck Anxiety Inventory) it may be better to use a shorter general measure of distress (e.g., General Health Questionnaire, ref).

Based on sample sizes for a definitive trial, we recommend the Western Ontario and McMaster Universities Osteoarthritis Index (pain subscale) as the primary outcome measure, for which a sample size of 133 per group is needed. Taking into account the attrition rate, the study would need to randomise 222 participants.

As a feasibility trial, outcomes were assessed only short-term (4- and 6-months after randomisation). Some participants were confused about having to answer the same set of questionnaires twice within two months. Therefore, for a Phase III randomised controlled trial we propose that the first outcome assessment is conducted at 6-months post-randomisation, when most participants would have recovered from the operation; and the second at 12-months post-randomisation, which will allow for the assessment of the longevity of the treatment effects. Another option would be to consider conducting the outcome assessments 6 and 12 months after the surgery itself. This way, if surgeries

are delayed, the outcomes would be collected at a similar point of recovery from the surgery for all participants. However, if delay of surgery were not random (for example, if the intervention contributed to delayed surgery), outcome assessments scheduled according to the date of surgery might not accurately reflect the outcome of the integrated treatment package. Irrespective of timing of outcome assessments, strategies to improve response rates of outcome questionnaires should be considered. We did not have an active control group (e.g., attention placebo group), which may have led to overestimating the intervention effects, and demand characteristics in the intervention group may have played a meaningful role in intervention-control differences. However, as this was a feasibility trial, where the objective was to test the feasibility of delivery of the intervention within a trial, it was appropriate not to have an attention placebo control group, which itself poses challenges in the randomised controlled trials of complex interventions.[36]

Our findings suggests that it is feasible to conduct a Phase III randomised controlled trial to evaluate whether providing psychological intervention while patients with knee osteoarthritis are on a waiting list for total knee arthroplasty is clinically and cost-effective. Recruitment from clinics was feasible, the outcome measures were acceptable, and the post-randomisation retention rates were adequate. While the majority of the procedures used in this trial would be suitable for a Phase III randomised controlled trial, three key changes are needed. First, the research sites selected need staff dedicated to recruit participants. Second, to ensure the intervention is completed before surgery, it is limited to 3-4 sessions, with the therapist identifying which key aspects to address in the sessions. Third, outcomes are assessed at 6 and 12-months post-

randomisation or following surgery, to allow for delays to surgery and for participants to recover from surgery. Furthermore, to ensure a good response rate to outcome measures, strategies such as online or telephone-completion of questionnaires must be considered. These changes notwithstanding, our findings suggest that a brief psychological intervention is an acceptable and feasible treatment for some participants that could improve outcomes from joint replacement surgery.

Clinical Messages

- Brief psychological intervention (based on cognitive behavioural therapy) is an acceptable and feasible treatment that could improve patient outcomes following knee surgery.
- A focused psychological intervention in 3-4 weekly sessions is required to permit delivery before patients have their surgery.
- Psychological intervention should be focused on the key aspects related to the individual patients' mood.

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Authors' contributions

RdN, SC, PL, BES, DAW, & NBL designed the study. JMM was the trial coordinator. JMM, GT, PL, and RdN analysed the qualitative data and NBL analysed the quantitative data. PA and SG designed and analysed the health economic data. HC and SC delivered the intervention. All authors were involved in the interpretation of the data, drafted sections or critically revised the work, and all have approved the final version to be published.

Competing interests

None of the authors have any competing interests with regards to this study.

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Table 1. Participant characteristics

	Control group n=25		Intervention group n=25	
	n	%	n	%
Gender				
Men	16	64	11	44
Women	9	36	14	56
Occupation				
Not employed	2	8	4	16
Retired	17	68	17	68
Employed full-time	6	24	2	8
Employed part-time	0	0	2	4
Ethnicity				
White British	25	100	24	96
Black or Black British	0	0	1	4
Index of Multiple Deprivation Score (2015)				
1 (most deprived)	3	12	2	8
2	2	8	4	16
3	3	12	6	24
4	9	36	4	16
5	1	4	3	12
6	5	20	5	20
7	0	0	1	4
8 (least deprived)	2	8	0	0
Previous total knee replacement				
Yes	10	40	7	28
No	13	52	15	60
Missing	2	8	3	12
	Mean	SD	Mean	SD
Age	66.7	9.9	65.7	8.6
HADS subscale scores				
Anxiety	8.1	3.1	9.8	3.8
Depression	10.5	4.0	10.3	4.0

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Table 2. Missing items and success of obtaining items by telephone follow-up

Measure (total number of items)	Baseline				4 month				6 month			
	Items missing		Items obtained by telephone follow-up		Items missing		Items obtained by telephone follow-up		Items missing		Items obtained by telephone follow-up	
	n	%	n	%	n	%	n	%	n	%	n	%
Intermittent and Constant Osteoarthritis Pain scale	0/550	0	N/A*	N/A*	16/330	5	11/16	69	11/275	4	11/11	100
Western Ontario and McMaster Universities Osteoarthritis Index	56/1200	5	49/56	88	33/720	4.5	24/33	72	31/600	4	24/31	77
Beck Depression Inventory	4/1050	0.4	0/4	0	42/630	7	21/42	50	43/525	8	0/21	0
Beck Anxiety Inventory	4/1050	0.4	1/4	25	42/630	7	21/42	50	43/525	8	0/21	0
EQ-5D-5L™	5/300	2	2/5	40	2/180	1	0/2	0	0/150	0	0	0
Total	0		52		4		77		6		35	

The numerator is the total number of items missing, the denominator is the total number of items for the whole dataset at that time point (At baseline n=50, at 4 month n=30, and at 6 months n=25). *N/A because there were no missing data at this time point for this scale. The numerator is the amount of items that were collected over the telephone; the denominator is the total number of missing items for that scale for that time point. The percentage reflects the amount of missing data that could be obtained over the telephone.

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Table 3. Comparison of outcomes by group allocation

Measure	**Time	Control			Intervention			*p*	Cohen's *d*
		n	Mean	SD	n	Mean	SD		
Intermittent and Constant Osteoarthritis Pain scale									
Constant pain (standard score for items 1–5)*	T1	13	9.5	5.6	16	9	5.6	0.83	0.08
	T2	12	6.2	3.2	13	6.2	4.4	0.99	0.005
Constant pain (standard score for items 1,3,4,5) *†	T1	13	7.9	4.6	16	7.0	4.4	0.62	0.19
	T2	12	5.1	3.0	13	4.8	3.7	0.82	0.09
Constant pain (converted Rasch score for items 1,3,4,5) ‡	T1	13	8.5	4.7	16	7.7	4.7	0.66	0.17
	T2	12	6.0	3.2	13	5.5	4.1	0.75	0.13
Intermittent pain (standard score for items 6–11)*	T1	13	14.3	4.6	17	11.0	5.3	0.09	0.66
	T2	12	10.2	4.5	13	8.5	5.6	0.43	0.32
Intermittent pain (standard score for items 6,7,10,11)*†	T1	13	9.7	3.1	17	7.4	3.5	0.07	0.71
	T2	12	7.1	3.3	13	5.7	3.8	0.33	0.39
Intermittent pain (converted Rasch score for items 6,7,10,11)* ‡	T1	13	9.1	2.7	17	6.9	3.2	0.06	0.74
	T2	12	6.7	3.0	13	5.5	3.4	0.34	0.39
Western Ontario and McMaster Universities Osteoarthritis Index									
Pain*	T1	13	8.38	4.1	17	9.1	4.4	0.67	-0.16
	T2	12	7.5	2.3	13	6.5	3.6	0.40	0.35
Stiffness*	T1	13	4.2	2.1	17	4.29	1.5	0.84	-0.08
	T2	12	4.2	0.9	12	3.2	1.9	0.11	0.67
Physical function*	T1	13	32.9	15.3	17	31.3	14.9	0.77	0.11

	T2	12	32.0	4.8	13	20.9	12.7	0.009*	1.16
Beck Depression Inventory									
Standard total score	T1	13	12.0	7.4	16	10.3	6.9	0.57	0.24
	T2	12	11.4	9.1	12	8.3	6.5	0.43	0.40
Rasch converted score	T1	13	15.9	2.8	16	14.7	3.4	0.26	0.39
	T2	12	15.1	3.1	12	12.7	5.9	0.50	0.52
Beck Anxiety Inventory total score	T1	13	9.4	7.0	16	8.1	8.2	0.42	0.17
	T2	12	8.7	9.2	12	6.0	4.4	0.95	0.37

Note: Higher mean scores indicate worse pain, functional limitations and mood. *denotes variables which were normally distributed. Normality was assumed if Z Skew and / or Z Kurtosis scores were between ±1.96 for small sample sizes (n < 50) or between ±3.29 for larger sample sizes (50 < n < 300). ǂ Following Moreton et al. [29] - removed item 2 from Constant pain subscale and items 8 and 9 from the Intermittent Pain subscale. Raw total subscale scores were converted to an interval scale (0 to 16) using Rasch score values provided. ǂ Converted score (original units) = m + (s * logit score). Where: s = (wanted range) / (current range), m = (wanted minimum) – (current minimum * s). **Time: T1=4 months follow-up, T2=6 months follow-up

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Table 4. Power and sample size calculations based on questionnaire descriptive statistics

	6 months				Total sample size required*	Return rate		Sample size required if take into account attrition rate$^{\phi}$	
	Control group n=12		Intervention group n=13			Control group	Intervention group	Per group	Total
	Mean	SD	Mean	SD					
Intermittent and Constant Osteoarthritis Pain scale									
Constant pain (standard score items 1-5)	6.17	3.22	6.15	4.71	1243664	12/20=60%	13/21=62%	1036387	2072773
Constant pain (standard score items 1,3,4,5)	5.08	3.00	4.77	3.72	3560			2967	5934
Constant pain (Converted Rasch score items 1,3,4,5)	6.00	3.17	5.53	4.13	1874			1562	3124
Intermittent pain (standard score items 6-11)	10.17	4.49	8.54	5.56	302			252	504
Intermittent pain (standard score items 6,7,10,11)	7.08	3.29	5.69	3.77	206			172	344
Intermittent pain (converted Rasch score items 6,7,10,11)	6.73	2.96	5.48	3.41	206			172	344
Western Ontario & McMaster Universities Osteoarthritis Index									
Pain	7.5	2.32	6.46	3.57	266		13/21=62%	222	444
Stiffness	4.17	0.94	3.17	1.9	76		12/21=57%	67	134

Physical function	32.00	4.79	20.85	12.73	32	13/21=62%	27	54
Beck Depression Inventory								
Standard total score	11.42	9.11	8.25	6.52	198	12/21=57%	174	348
Rasch converted score	15.07	3.07	12.65	5.85	120		105	210
Beck Anxiety Inventory total score	8.67	9.16	6.00	4.34	226		198	396

*Continuous outcome test to test for superiority (intervention vs control). Calculation based on significance level (alpha) of 5%, power (i-beta) of 80%. Mean outcome in control group, mean outcome in experimental group, standard deviation (total sample) of outcome at 6months (see link: https://www.sealedenvelope.com/power/c11.13ontinuous-superiority/). ϕ Based on higher attrition (the lower response rate between the intervention and control group - in the two columns on the left).

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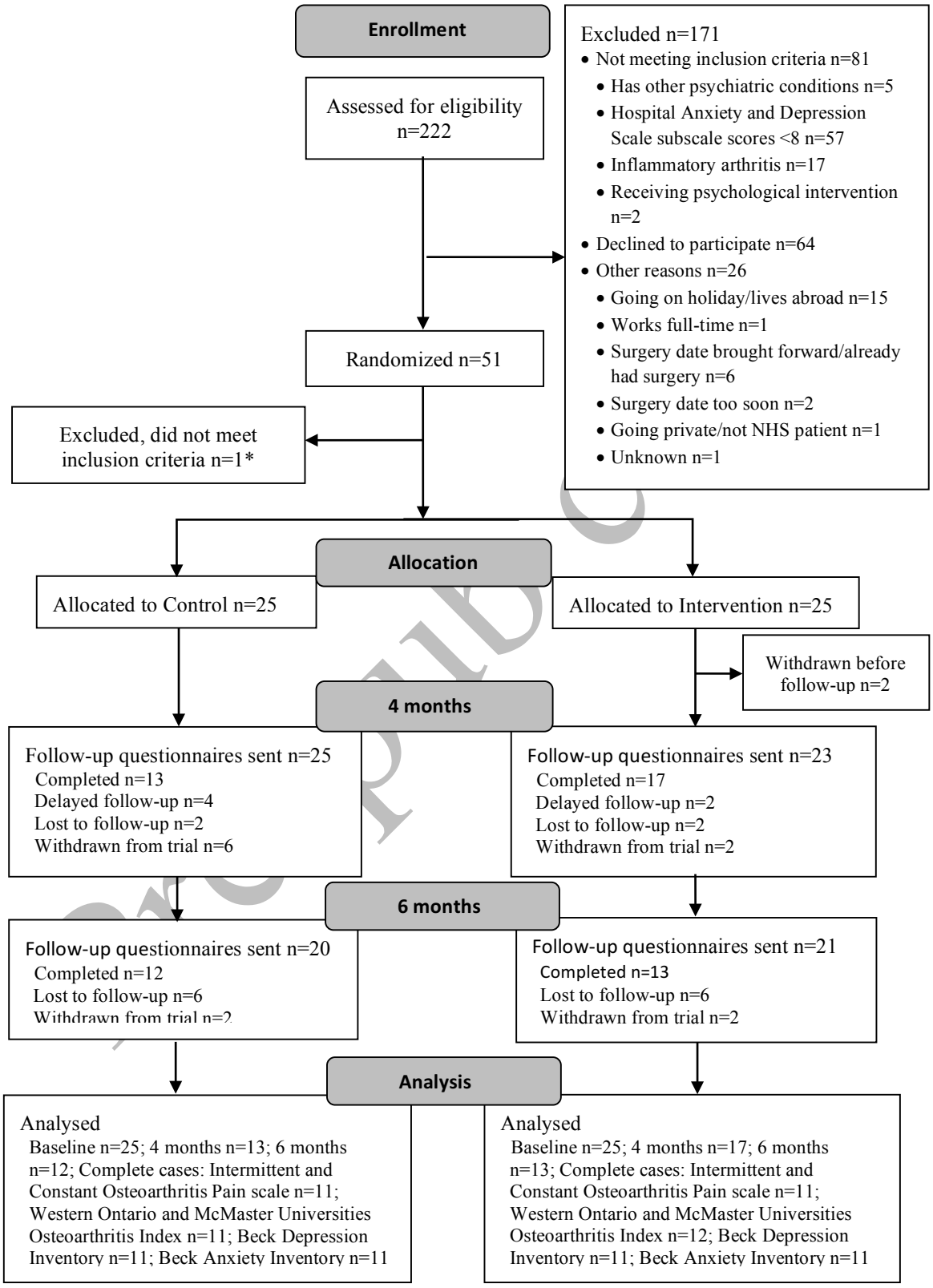
Figure 1. CONSORT diagram



*Included in error, due to miscalculated screening score.

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Supplementary Document 1 – Service use questionnaire

In the past 3 months on how many occasions have you been to visit a health professional:

	Because of your joint problems (enter number and reason)	**Because of other reasons (enter number and reason)**
Example: Consulted the GP at the practice	Number of times: 1 Reasons: pain and swelling in left knee	Number of times: 2 Reasons: stomach bug; and chest infection
Consulted the GP at the practice	Number of times: _____ Reasons: _____	Number of times: _____ Reasons: _____
Visited the Practice Nurse at the practice	Number of times: _____ Reasons: _____	Number of times: _____ Reasons: _____
Been to consult or visited by other health and social care professionals (e.g. physiotherapist, osteopath, occupational therapist, psychologist, podiatrist/ chiropodist, orthotist, dietician, etc.)	Number of times: _____ Reasons: _____ Which professionals did you see: _____ Where did you see them? _____	Number of times: _____ Reasons: _____ Which professionals did you see: _____ Where did you see them? _____
Been a hospital in-patient	Number of times: _____ Reasons: _____ Days spent in hospital: _____ Was this a medical or surgical ward? _____	Number of times: _____ Reasons: _____ Days spent in hospital: _____ Was this a medical or surgical ward? _____

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Visited hospital Outpatient Department	Number of times: _____ Who did you see there? _____ Reasons: _____ _____	Number of times: _____ Who did you see there? _____ Reasons: _____ _____

In the past 3 months on how many occasions have you <u>been visited at home by</u>:

	Because of joint problems (enter number and reason)	**Because of other reasons (enter number and reason)**
GP visited you at home	Number of times: _____ Reasons: _____ _____	Number of times: _____ Reasons: _____ _____
Community Nurse visited you at home	Number of times: _____ Reasons: _____ _____	Number of times: _____ Reasons: _____ _____
Other health and social care professionals visited you at home (e.g. physiotherapist, osteopath, occupational therapist, psychologist, podiatrist/ chiropodist, orthotist, dietician, etc.)	Number of times: _____ Reasons: _____ _____ Which professionals did you see: _____ _____	Number of times: _____ Reasons: _____ _____ Which professionals did you see: _____ _____

Are you currently on any medication for your joints or other problems? **YES / NO** (If YES, please list all medications)

1		6	
2		7	
3		8	
4		9	
5		10	

Have you have started and/or stopped in the last 3 months? **YES / NO** (If YES, please list medication)

Medication Started within the last 3 months:	*Medication stopped within the last 3 months:*

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Are you suffering from any other complaints or illnesses besides your joint problems?
YES / NO (If yes, please list any illnesses and year of diagnosis)

_____ _____
_____ _____

What is your current employment status? (Please tick)

☐ Not employed
☐ Retired
☐ Employed full-time*
☐ Employed part-time*
☐ In Education full-time
☐ In Education part-time

*Includes self employed

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Supplementary Document 2. Emerging codes and categories, their descriptors and illustrative examples.

Themes	Sub-themes	Description	Illustrative quotes
Experience of being in the study	Understanding Rationale	Clarity of the study rationale	*"Well, as far as I could see, it [the study] was how […] I was going to cope with it [knee pain] mentally and physically, before and after my operation."* (Interview 4, M, face to face, Intervention group)
	Understanding research process	Clarity of the information provided	*"I thought it [participant information sheet] was very well put-together. If I couldn't understand it too much, then I'd have probably said I wouldn't have continued with it [the study] […] Like you said, you know, I don't have to take part if I didn't want to."* (Interview 4, M, face to face, intervention group)
		Acceptability of the recruitment process	*"And that's when they [research nurse in orthopaedic clinic] asked you to fill the questionnaire [screening questionnaire], and you didn't really know what it was about or anything […], we didn't know at first. You know, well, she [research nurse] probably explained a little bit about it, but it didn't sink in. You know, 'cause you've got other things on your mind at the time […] 'cause everything was happening. You know, all my other hospital appointments and all this. So…yeah, you know, you didn't take it all in."* (Interview 12, M, face to face, intervention group)
		Acceptability of the randomisation protocol	

			"Interviewer: *If you had been randomly put into this group that didn't receive the treatment, and just received the questionnaires, how would you have felt about that?* ***Respondent:*** *I don't know because I was lucky enough, wasn't I, to get the different ones? So I suppose – I still would have filled your questionnaire in […] and hope that we'd gain something from it, or you would gain something from it."* (Participant 19, F, telephone, intervention) *"I had the pre-op, that's where the lady [research nurse] first talked about this, because she [research nurse] says 'you're a candidate for this HAPPiKNEES thing', but that's all, since then, between then and the surgery, nothing. I would have liked to have, you know, sort of, I suppose it would be a bit of reassurance and that sort of thing…"* (Participant 8, M, face to face, control)
Outcome measures	Focus of measures	Appropriate	*"Yeah, it [questionnaire] covered everything. I kept thinking some of the questions, I thought oh yeah, you know, you could relate to it."* (Interview 5, M, face to face, control)

		Not appropriate	*"[…] you know, it's a knee operation. It's not a – you've not got cancer. If it was cancer or something that was life-threatening, or something that was disfiguring, I could understand the questions [BDI and BAI] more."* (Interview 22, F, telephone, intervention group)
	Quantity	Adequate number of questions	*"As I say, they're quite straightforward and gave you the variety of choices."* (Interview 22, F, telephone, intervention group)
		Too many questions	*"I think there was too many [questionnaires] personally and I think that would probably put a lot of people off […] especially somebody on their own, with two of us, we looked at it and went through it together, but I can imagine if somebody was on their own looking at that they'd 'oh', you know, 'I can't be bothered' […] I think people will fill forms in, the least they are the better […] I think people just get fed up with filling forms in. Whereas if it's just a quick couple of pages, I don't think people will mind so much"* (Interview 8, M, face to face, control group)
		Repetitions	*"They asked the right questions but they were asking about – one question about four different ways. You know what I mean? […] Which I think was a bit balmy."* (Interview 15, M, telephone, control group)

	Quality	Positive views (ease of completion and understanding) Negative views (contradictory, duplications, difficulty in understanding questionnaires)	*"Yeah, they [questionnaires] were fine. Yeah, quite easy to fill in. No problems. Straightforward"* (Interview 1, F, face to face, control group) *"The forms [questionnaires, yeah. I'm almost certain them forms were too many […] I've never been any good with at school like I was saying and these questions they're bloody hard some of them. I can't, I'm not very good at spelling. I'll be truthful…"* (Interview 17, M, telephone, intervention group)
	Timing of the questionnaires	Concerns about the timing when they received the questionnaire (soon after surgery)	*"I found it [timing of the questionnaires] all right, but I don't know if I filled that [questionnaire] in 'correctly', because if I'd have filled that in before I'd had my operation, the answers to my questions might have been different […] But because I've had my knee done and I'm in that much pain, and it's saying to you 'in the last so many weeks, how have you felt?' […] Because of my negative thoughts, you see, because of – how the question's worded and how you've got to answer, and I try to answer as truthfully as I can because over the past through weeks, how has it been? But it was a few weeks after I'd had the operation, so you got the moany one, whereas you might have got a better one before I'd had it done."* (Interview 19, M, telephone, intervention group)

		Confusion about filling in the questionnaires at follow-ups	*"And then I when I received your letter about the pain […] I didn't realise it [questionnaire] was post-op. You know what I mean? […] I sent it [questionnaire] back. I'd already had the surgery […] I thought, well, I've had the surgery now. Why do they want…? You know […] And I thought, 'Oh, they've probably overlooked it and sent it [questionnaire] me again. Maybe they lost the other one or something.' […] did it [cover of questionnaire] say post-surgery on it, or not? If you'd highlighted that a little bit more"* (Interview 14, M, face to face, intervention group)
	Specific comments on specific outcome measures	ICOAP (confusion over the constant and intermittent pain subscales) Mood questionnaires (connection unclear between TKR and mood questionnaires)	*"Yeah I did find some of it [questions] a bit strange cos you see, I mean the first one 'How intense is your constant knee pain?' and I tried to separate constant because I didn't get really intense constant, I mean I suppose everybody's different aren't they so what's going to be relevant to some isn't to others. Mine's more of like a nagging, always there, yeah. The constant knee pain threw me a bit cos it, it comes and goes and it can depend on what you've done the day before or I sometimes wonder what I've eaten or yeah." (Interview 6, F, face to face, intervention group)*

		EQ-5D (unclear whether EQ-5D questions were specific to OA or general health, confusion over too many options)	*"Some of these questions I found a bit strange like agitation and loss of interest, you know, I find those a bit, I suppose some people might do, like worthlessness, I do not feel I am worthless, you know, questions like that, I mean, I don't know if, I just find those a bit strange, them [sic] questions. I suppose some people might but why would having knee replacement make you feel worthless? I don't know. Well, I mean, I did try to answer everything as much as I can […] It seemed like this, feelings of choking, you know, what's that got to do with a knee replacement!"* (Interview 8, M, face to face, control group) *"So I was itching, all these hives and they were like, I'd got them in my ears didn't I? And I sat and I thought well I'm going to get this out the way but how am I focusing on these when I've got all this. And then I think there was one bit in the survey where it said 'And how do you rate yourself today?' or something […] At the end, is it the one with the ruler, on a scale of zero to a hundred or something, how good is your health today […] And I thought well that, cos I thought, and this survey it was really difficult to do because I'd got extra problems other than – is this my survey or is this another one?"* (Interview 6, F, face to face, intervention group)

		Service use questionnaire	*"Some of the questions – like, you've got that many options; it confuses you a little bit. It [questionnaire instructions] does say don't think about it too long, doesn't it? Like, you know, try and read them and give your answer […] It was it on the last page, where you've got that chart [EQ-5D visual analogue scale] thing? […] Yeah, I think probably sometimes you've answered one question and you go onto one probably two or three bits later on and I think, 'Well, am I going to contradict myself here, or what?' You know what I mean?"* (Interview 14, M, face to face, intervention group) *"I think perhaps I felt that there wasn't quite enough space [on questionnaire]. But I've been back for several other things and there wasn't quite enough room there [on questionnaire]."* (Interview 6, F, face to face, intervention group)
Treatment experience	Rationale (understanding and acceptance of CBT)	Understanding of the relationship between thoughts, mood and pain	*"Well, I guess my thought process was how I dealt with pain. That to me was enlightening. Then when I went to the talking session, I found that useful with we sort of talked about relaxation and anxieties and questions that may have come up. So that was useful and I think that's something that I've kept with me when I've been in pain about being more*

		Misunderstandings about when the CBT should/did occur (perception that therapy should have been provided after surgery)	*relaxed."* (Interview 13, F, telephone, intervention group) *"And then a nurse [research nurse] came and took all my details then and then [therapist] came pretty quickly after, probably only just over a week, I think it was less than a fortnight I went on the programme, so I suppose I was a bit early really, cos obviously there was no operation date mentioned and I'd have finished the programme well before the operation. And I did say to [therapist] at the time when I did it, I felt it [therapy] would have been more useful afterwards, after the operation but obviously you don't do that at the moment."* (Interview 6, F, face to face, intervention group)
		Understanding of CBT (CBT as a common sense, e.g. having a bit of a chat)	*"[…] 'cause it's – that's nice, when somebody will come out and have a chat with you about things like this [referring to the content of the CBT sessions]. I think that's very, very good. […] Instead of just going into it [surgery].That does actually help. It [session with therapist] gives you a bit of…how can I put it? It gives you a bit of gall. It mean – what I'm trying to say is that chat helped me to go and actually get it [surgery] done"* (Interview 20, F, face to face, intervention group)
		Concerns about what benefit it might offer	

		Disagreement with the thoughts-mood-pain interaction	*"I found it [therapy sessions] a bit deep if anything because I don't see how you can manage pain when you don't know what is going to happen. I mean it's alright saying you can manage pain, but you can't manage pain unless you've got some form of medication."* (Interview 10, M, telephone, intervention group) *"[…] to me, the pain I've suffered with my knees, I find it difficult to accept that a lot of it's in your mind, sort of thing, like – you know. […] It [therapy] was saying 'mind over matter'. Your brain sends a signal and it's the brain telling you that you're in pain and all that sort of thing. And I can understand that, but it don't help you when you're in pain in my opinion, like, anyway. And a lot of it can be mind over matter, but it depends how much pain you've got."* (Interview 14, M, face to face, intervention group)
	Perceived benefits of CBT	Example benefits: Reassurance, relaxation, calmness, positive thoughts, thinking differently, having more realistic expectations	*"Sometimes I'm finding myself walking and I'm really tense so I say to myself 'relax, relax' and I've found that that helps. So I guess that's something that I've taken away with me from doing one of the sessions […] Right, OK. Well, I guess my thought process was how I dealt with pain. That to me was enlightening. Then when I went to the talking session, I found that useful with we sort of*

			talked about relaxation and anxieties and questions that may have come up. So that was useful and I think that's something that I've kept with me when I've been in pain about being more relaxed." (Interview 13, F, telephone, intervention group)
		No perceived benefit of CBT	*"I thought it [CBT] was different to what it is […] I don't know. […] I've had two sessions of physiotherapy – by that I mean I've met the physiotherapist and she's taught me different exercises, and I've found that more helpful […] Yeah, I found that more useful – more – even though, when I do the exercises, I do know that I've done them, but I've found that is – at least I know I'm getting somewhere, or I think I'm getting somewhere."* (Interview 22, F, telephone, intervention group)
		Need for post-surgery reminders to help remember what they learned during the sessions	*"What about a tape or something that you could just put on and think, 'Oh, I'll just refresh my mind and everything with that'? That's only a thought. That's only me. […] Yeah, when I last saw [therapist], I definitely – I'm not saying everything worked 'cause, I mean, we're all individuals, but I did start and think of more positive things, and I did, when I went to the hospital, think, 'Now—' you know, 'cause it's a little bit daunting. It's early in the morning, blah, blah, and I did think, 'Now,*

			don't forget what you've been told. Relax and….' And I did. You know. But since I've been home and I'd – there aren't been many positive thoughts. I have thought, occasionally, when it's been a bit easier, 'Oh, well, you're on the mend', but then I've had a set-back and the good thoughts get pushed really, really back. But if we've got something to jog our memories. You know: don't be negative; be positive." (Interview 19, M, telephone, intervention group)
	Perceived mediators of change	CBT-specific input (e.g., relaxation and distraction techniques)	*"I mean for me the main thing [benefit of therapy] was the relaxation and having a positive outlook […] The relaxation […] was about centring [sic] on your breathing and not tensing, especially when walking, not hunching your shoulders and it talked about being in a darkened room and moving through and centring on your breathing and releasing the pain from your body."* (Interview 13, F, telephone, intervention group)
		General therapy/therapist factors (e.g., personalisation of therapy, reassurance of an expert voice)	*"No it was all helpful. But saying that it may be because looking back I perhaps steered [therapist] to what was happening to me at that time. So [therapist] gave me advice personal to me in a way that was like the time management and pacing and breaking things down, to do things when, the physical stuff perhaps when the pain was less and then do*

		Other factors (e.g. information provision, sign-posting)	*my crafts when it was quite painful because it would wear off if I'm doing something else, obviously, so not to have too much of a set pattern was useful, just different ways of looking at how I was doing things."* (Interview 6, F, face to face, intervention group) *"I enjoyed having the one to one sessions. […] it was a good way to prepare and get a mindset of having a big operation. And I felt there was a little bit of extra support there as well, apart from obviously just having the consultant, but I felt by going to the sessions if there was something I was worried about, somebody would say 'oh, you can ask the physio'. It was nice having that little bit of extra support."* (Interview 13, F, telephone, intervention group)
	Format of treatment sessions	Home or hospital setting (home for pragmatic reasons [time, transport and mobility issues] & hospital for work obligations [easier to attend during the day]) Group vs. individual treatment delivery	*"I would have gone to the hospital, but it's just, well, driving – you're not too keen on driving on motorways and dual carriageways, so it's better at home, for me."* (Interview 12, M, face to face, intervention group) *"Possibly but I think sometimes you can get intimidated, if you know what I mean, some people kind of demand the stage, if you know what I mean […] And then other people who need to ask questions don't because they're frightened of being thought to be stupid or*

			something, you know. So I think it really depends and obviously you will always get a mixture of patients so you're going to get this mixture of somebody who's really bombastic and then somebody who's very timid." (Interview 9, F, face to face, intervention) *"I probably think it [therapy] would be better in a group […] To be honest because I think, like I say, different people have got a different way of interpreting things and I think as a group you could probably talk about it and get more out of it that way."* (Interview 10, M, telephone, intervention group)

Note. Quotes are followed by a description of interview number, gender of the participant (M or F), whether the interview was conducted face-to-face or over the telephone, and whether the participant was allocated to the intervention or control group.