Clinical trial results:
Improving outcomes for patients with hip osteoarthritis: a randomised controlled trial

Summary

EudraCT number	2014-003412-37
Trial protocol	GB
Global end of trial date	19 December 2018

Results information

Result version number	v1
This version publication date	04 January 2020
First version publication date	04 January 2020

Trial information

Trial identification

Sponsor protocol code	323/12

Additional study identifiers

ISRCTN number	ISRCTN50550256
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Keele University
Sponsor organisation address	Keele, Newcastle-under-Lyme, United Kingdom, ST5 5BG
Public contact	Study co-ordinator, Keele University, 44 01782734875, a.cherrington@keele.ac.uk
Scientific contact	Study co-ordinator, Keele University, 44 01782734875, a.cherrington@keele.ac.uk

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	03 June 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 December 2018
Global end of trial reached?	Yes
Global end of trial date	19 December 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this trial is to compare longitudinal average mean pain scores over 6 months in people with hip osteoarthritis between those receiving best current treatment in addition to a steroid and local anesthetic injection with those receiving best current treatment alone.

Protection of trial subjects:

The trial was performed in accordance with the recommendations guiding physicians in biomedical research involving human subjects adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964, amended at the 52nd World Medical Association General Assembly, Edinburgh, Scotland. Informed written consent was obtained from the participants prior to any trial-specific procedures taking place. The right of a participant to refuse participation without giving reasons was respected. The trial was submitted to and approved by a main NHS Research Ethics Committee (main REC) and the appropriate site approvals given for each participating centre prior to entering participants into the trial. Subsequent amendments were approved by the Health Research Authority (HRA), main REC and MHRA as required. All information collected during the course of the trial is kept strictly confidential. Keele CTU complied with all aspects of the applicable Data Protection Act.

Background therapy:

None

Evidence for comparator:

Best current treatment comprised verbal and written information to enhance understanding of osteoarthritis and its management, and provide personalised advice and information about weight loss, exercise, footwear, walking aids and optimising pain management, consistent with the National Institute for Health and Care Excellence (NICE) osteoarthritis care and management clinical guideline (CG 177, published February 2014)). https://www.nice.org.uk/guidance/cg177

Triamcinolone acetonide has a well-established safety profile and was used at the dosage and form detailed in the Summary of Product Characteristics (SPC). It is licensed for use in osteoarthritis and is widely used for this purpose in clinical practice. There is one published randomised trial of an intra-articular injection of triamcinolone acetonide for hip osteoarthritis, which showed that triamcinolone acetonide 80mg produced greater reduction in pain than 1% mepivocaine (Kullenberg J Rheumatol 2004;31(11):2265–8).

1% lidocaine hydrochloride is licensed for regional anaesthesia and the dosage used in the trial is within current established practice as detailed in the Summary of Product Characteristics (SPC). There is one published randomised trial in which intra-articular injection interventions for hip osteoarthritis included 1% lidocaine hydrochloride, finding that 1ml 1% lidocaine hydrochloride plus saline water was less effective than 1ml 1% lidocaine hydrochloride in combination with a corticosteroid (methylprednisolone acetate) (Qvistgaard 2006;14(2):163–70).

Actual start date of recruitment	01 October 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 199
Worldwide total number of subjects	199
EEA total number of subjects	199

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	113
From 65 to 84 years	83
85 years and over	3

Subject disposition

Recruitment

Recruitment details:

Participants were recruited from primary care referrals to orthopaedics, rheumatology and two musculoskeletal NHS interface services, and direct from primary care.

Pre-assignment

Screening details:

Potentially eligible patients were posted study information and invited to attend musculoskeletal hip clinics within two musculoskeletal interface services, where patients were screened, consented and treated.

Pre-assignment period milestones

Number of subjects started	199
Number of subjects completed	199

Period 1

Period 1 title	Trial recruitment and follow up (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Data analyst[1]

Blinding implementation details:

Participants and clinicians were not blind to allocation to BCT alone, or, BCT plus injection. However, for those participants randomised to either of the two injection arms, participants and non-injecting clinicians were blind to the exact nature of the injection (triamcinolone acetonide plus 1% lidocaine hydrochloride or 1% lidocaine hydrochloride alone). The statisticians and research nurses (who conducted minimal data collection) were blind to allocation.

Arms

Are arms mutually exclusive?	Yes
Arm title	Best Current Treatment

Arm description:

BCT comprised written information (Arthritis Research UK Osteoarthritis leaflet and a bespoke leaflet on exercise and functional activities), personalised advice and information about weight loss, exercise, footwear, walking aids and optimising pain management, delivered within the clinic visit.

Arm type	Control arm

No investigational medicinal product assigned in this arm

Arm title	BCT+US-L

Arm description:

Best Current Treatment (BCT) combined with an ultra-sound guided injection (USGI) of 5ml 1% lidocaine only.

Arm type	Active comparator
Investigational medicinal product name	1% lidocaine hydrochloride
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intraarticular use

Dosage and administration details:

Single intra-articular injection of 5mls 1% lidocaine hydrochloride into the hip

Arm title	BCT+US-T

Arm description:

Best Current Treatment (BCT) combined with an ultra-sound guided injection (USGI) of 40mg triamcinolone acetonide and 4ml 1% lidocaine hydrochloride.

Arm type	Experimental
Investigational medicinal product name	Triamcinolone acetonide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intraarticular use

Dosage and administration details:

Single intra-articular injection of 40mg triamcinolone acetonide into the hip (combined with 4mls 1% lidocaine hydrochloride)

Investigational medicinal product name	1% lidocaine hydrochloride
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intraarticular use

Dosage and administration details:

Single intra-articular injection of 4mls 1% lidocaine hydrochloride into the hip (combined with 40mg triamcinolone acetonide)

Notes:

[1] - The roles blinded appear inconsistent with a simple blinded trial.

Justification: Analysis was performed blind to treatment allocation. Subjects were blind to injection type but not whether or not they received an injection. Data collection was self reported but a blind assessor collected data from non responders.

Number of subjects in period 1	Best Current Treatment	BCT+US-L	BCT+US-T
Started	67	66	66
Baseline	67	66	66
2 weeks follow up	62	63	64
2 months follow up	58	65	64
4 months follow up	57	63	59 [2]
6 months follow up	56	61	61
Completed	56	61	61
Not completed	11	5	5
Adverse event, serious fatal	-	-	2
Consent withdrawn by subject	7	2	3
Lost to follow-up	4	3	-

Notes:

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Participants who did not return follow up data at interim timepoints were permitted to return follow up data at a later time point.

Baseline characteristics

Reporting groups	
Reporting group title	Best Current Treatment
Reporting group description:	
BCT comprised written information (Arthritis Research UK Osteoarthritis leaflet and a bespoke leaflet on exercise and functional activities), personalised advice and information about weight loss, exercise, footwear, walking aids and optimising pain management, delivered within the clinic visit.	
Reporting group title	BCT+US-L
Reporting group description:	
Best Current Treatment (BCT) combined with an ultra-sound guided injection (USGI) of 5ml 1% lidocaine only.	
Reporting group title	BCT+US-T
Reporting group description:	
Best Current Treatment (BCT) combined with an ultra-sound guided injection (USGI) of 40mg triamcinolone acetonide and 4ml 1% lidocaine hydrochloride.	

Reporting group values	Best Current Treatment	BCT+US-L	BCT+US-T
Number of subjects	67	66	66
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	37	39	37
From 65-84 years	28	26	29
85 years and over	2	1	0
Age continuous Units: years			
arithmetic mean	63.7	62.3	62.5
standard deviation	± 10.9	± 9.8	± 9.3
Gender categorical Units: Subjects			
Female	42	36	35
Male	25	30	31
Centre Units: Subjects			
Haywood	57	56	50
Cannock	10	10	16
Ethnic group			
Ethnic group question: Which group do you consider yourself to belong to? White Non-white = Black/African/Carribean/Black British or Asian/Asian British or Mixed/multiple ethnic groups or Other			
Units: Subjects			
Non-white	0	1	0

White	67	65	66
Living alone Units: Subjects			
No	57	53	57
Yes	10	13	9
Currently employed Units: Subjects			
No	10	10	6
No, retired	30	29	23
Yes	25	26	37
Missing data	2	1	0
Smoking status Units: Subjects			
Never	33	29	35
Previous	24	24	21
Current	10	13	10
Alcohol consumption Units: Subjects			
Daily / most days	12	7	12
Once or twice a week	22	31	25
Once or twice a month	16	9	11
Once or twice a year	7	8	12
Never	10	11	6
Hip(s) affected			
Over the last 12 months, pain in which hip(s)			
Units: Subjects			
Both	16	19	14
Right only	32	30	28
Left only	19	17	24
Duration of symptoms			
Over the last 12 months, how many days had pain			
Units: Subjects			
Less than 3 months	2	1	3
Between 3 months and 6 months	8	4	5
Between 6 months and 1 year	19	14	9
More than 1 year	38	47	48
Missing data	0	0	1
Days of pain in last 12 months			
Over last 12 months, how many days in pain			
Units: Subjects			
Less than 7 days	0	1	0
1-4 weeks	0	0	0
More than 1 month but less than 3 months	4	2	6
3 months or more	63	63	60
Previous hip injury			
Ever injured hip badly enough to see a doctor about it			
Units: Subjects			
No	59	55	58
Right hip only	2	5	4
Left hip only	2	5	3

Both hips	3	1	1
Missing data	1	0	0
Sleep problems			
During past 4 weeks, troubled by pain from hip in bed at night			
Units: Subjects			
No nights	6	2	1
Only 1 or 2 nights	2	5	3
Some nights	19	10	10
Most nights	19	19	24
Every night	21	30	28
Previous hip injection			
Ever had steroid injection(s) into hip(s)?			
Units: Subjects			
No	64	63	65
Yes	3	3	1
Injection to other joint			
Ever had a steroid injection into a joint other than the hip			
Units: Subjects			
No	48	43	40
Yes	19	23	25
Missing data	0	0	1
Preference			
Treatment preference			
Units: Subjects			
To have a hip injection	62	61	62
Not to have a hip injection	5	3	3
Missing data	0	2	1
Comorbidity			
Other health conditions			
Units: Subjects			
No	20	19	29
Yes	47	46	36
Missing data	0	1	1
BMI			
Body Mass Index (kg/m2)			
Units: kg/m2			
arithmetic mean	29.5	28.2	29.8
standard deviation	± 6.7	± 4.5	± 5.9
Pain NRS			
How severe is hip pain today (0-10 scale; 0=no pain at all, 10=worst pain imaginable)			
Units: 0-10 scale			
arithmetic mean	5.7	5.7	5.8
standard deviation	± 2.2	± 2.1	± 2.1
WOMAC - Total			
Western Ontario and McMaster Universities Arthritis Index (WOMAC) - Total scale score (0-96 scale; 0=no prolems; 96=extreme problems)			
Units: 0-96 scale			
arithmetic mean	51.1	50.7	50.2
standard deviation	± 19.0	± 13.0	± 14.8
WOMAC-P			
Western Ontario and McMaster Universities Arthritis Index (WOMAC) - Pain subscale score (0-20 scale; 0=no pain, 20=extreme pain)			

Units: 0-20 scale			
arithmetic mean	10.7	10.7	10.7
standard deviation	± 4.0	± 3.2	± 2.8
WOMAC-S			
Western Ontario and McMaster Universities Arthritis Index (WOMAC) - Stiffness subscale score (0-8 scale; 0=no stiffness, 8=extreme stiffness)			
Units: 0-8 scale			
arithmetic mean	4.3	4.6	4.6
standard deviation	± 1.5	± 1.5	± 1.4
WOMAC-F			
Western Ontario and McMaster Universities Arthritis Index (WOMAC) - Function subscale (0-68; 0=no difficulty; 68=extreme difficulty)			
Units: 0-68 scale			
arithmetic mean	36.0	35.4	35.0
standard deviation	± 14.6	± 10.9	± 11.6
PSEQ			
Pain Self-Efficacy Questionnaire (0-60 scale; 0=no confidence; 60=highest confidence)			
Units: 0-60 scale			
arithmetic mean	35.7	38.5	36.4
standard deviation	± 14.7	± 13.0	± 13.4
IPQ			
modified brief Illness Perceptions Questionnaire (0-50 scale; 0=full understanding, 50=least understanding)			
Units: 0-50 scale			
arithmetic mean	30.7	29.9	29.8
standard deviation	± 7.2	± 5.4	± 7.3
IPQ-Consequences			
modified brief Illness Perceptions Questionnaire - Consequences subscale (0-10 scale; 0=no affect at all; 10=severely affects life)			
Units: 0-10 scale			
arithmetic mean	6.5	6.5	6.4
standard deviation	± 2.4	± 1.8	± 2.1
IPQ-Timeline			
modified brief Illness Perceptions Questionnaire - Timeline subscale (0-10 scale; 0=last very short time; 10=last forever)			
Units: 0-10 scale			
arithmetic mean	9.0	9.2	8.7
standard deviation	± 1.4	± 1.3	± 1.8
IPQ-Personal control			
modified brief Illness Perceptions Questionnaire - Personal control subscale (0-10 scale; 0=no control; 10=extreme control)			
Units: 0-10 scale			
arithmetic mean	3.6	4.1	4.2
standard deviation	± 2.8	± 2.9	± 2.6
IPQ-Treatment control			
modified brief Illness Perceptions Questionnaire - Treatment control subscale (0-10 scale; 0=treatment no help; 10=treatment extremely helpful)			
Units: 0-10 scale			
arithmetic mean	7.4	7.4	7.3
standard deviation	± 2.0	± 2.0	± 2.0
IPQ-Emotional response			
modified brief Illness Perceptions Questionnaire - Emotional response subscale (0-10 scale; 0=not affected emotionally; 10=extremely affected emotionally)			
Units: 0-10 scale			

arithmetic mean	6.1	5.7	6.1
standard deviation	± 2.9	± 2.8	± 2.7
EQ5D			
EuroQoL EQ5D (health utilit) (-0.59 to 1.00; [-0.59=worst health utility, 1.00=best health utility)			
Units: -0.59 to 1.00			
arithmetic mean	0.50	0.48	0.49
standard deviation	± 0.22	± 0.24	± 0.23
SF-12 PCS			
Short Form-12 Physical Component Scale (SF12_PCS) (0-100 scale; 0=worst physical health, 100=best physical health)			
Units: 0-100			
arithmetic mean	33.9	33.2	34.5
standard deviation	± 9.1	± 8.9	± 9.0
SF12-MCS			
Short Form-12 Mental Component Scale (SF12_MCS) (0-100 scale; 0=worst mental health, 100=best mental health)			
Units: 0-100 scale			
arithmetic mean	49.3	52.9	51.5
standard deviation	± 13.3	± 10.0	± 12.2
GAD-7			
Generalised Anxiety Disorder Assessment (7-item scale)			
Units: 0-21 scale			
arithmetic mean	6.1	5.3	5.9
standard deviation	± 6.3	± 5.8	± 5.9
PHQ-8			
Patient Health Questionnaire depression scale			
Units: 0-24 scale			
arithmetic mean	6.9	6.2	6.7
standard deviation	± 6.2	± 6.0	± 6.2
SPS			
Stanford Presenteeism Scale (6-30 scale; 6=minimum ability, 30=maximum ability)			
Units: score			
arithmetic mean	20.0	20.2	20.2
standard deviation	± 6.1	± 3.7	± 4.7
Work Performance			
Work Performance (Numerical Rating Scale (NRS), 0-10; 0=Not at all affected, 10=Pain so bad that unable to do job). Question worded: On average to what extent has your hip problem affected your performance at work in the last 6 weeks?			
Units: score			
arithmetic mean	3.9	5.2	4.7
standard deviation	± 3.3	± 2.8	± 2.4

Reporting group values	Total		
Number of subjects	199		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		

Adolescents (12-17 years)	0		
Adults (18-64 years)	113		
From 65-84 years	83		
85 years and over	3		
Age continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	113		
Male	86		
Centre			
Units: Subjects			
Haywood	163		
Cannock	36		
Ethnic group			
Ethnic group question: Which group do you consider yourself to belong to? White Non-white = Black/African/Carribean/Black British or Asian/Asian British or Mixed/multiple ethnic groups or Other			
Units: Subjects			
Non-white	1		
White	198		
Living alone			
Units: Subjects			
No	167		
Yes	32		
Currently employed			
Units: Subjects			
No	26		
No, retired	82		
Yes	88		
Missing data	3		
Smoking status			
Units: Subjects			
Never	97		
Previous	69		
Current	33		
Alcohol consumption			
Units: Subjects			
Daily / most days	31		
Once or twice a week	78		
Once or twice a month	36		
Once or twice a year	27		
Never	27		
Hip(s) affected			
Over the last 12 months, pain in which hip(s)			
Units: Subjects			
Both	49		
Right only	90		
Left only	60		

Duration of symptoms			
Over the last 12 months, how many days had pain			
Units: Subjects			
Less than 3 months	6		
Between 3 months and 6 months	17		
Between 6 months and 1 year	42		
More than 1 year	133		
Missing data	1		
Days of pain in last 12 months			
Over last 12 months, how many days in pain			
Units: Subjects			
Less than 7 days	1		
1-4 weeks	0		
More than 1 month but less than 3 months	12		
3 months or more	186		
Previous hip injury			
Ever injured hip badly enough to see a doctor about it			
Units: Subjects			
No	172		
Right hip only	11		
Left hip only	10		
Both hips	5		
Missing data	1		
Sleep problems			
During past 4 weeks, troubled by pain from hip in bed at night			
Units: Subjects			
No nights	9		
Only 1 or 2 nights	10		
Some nights	39		
Most nights	62		
Every night	79		
Previous hip injection			
Ever had steroid injection(s) into hip(s)?			
Units: Subjects			
No	192		
Yes	7		
Injection to other joint			
Ever had a steroid injection into a joint other than the hip			
Units: Subjects			
No	131		
Yes	67		
Missing data	1		
Preference			
Treatment preference			
Units: Subjects			
To have a hip injection	185		
Not to have a hip injection	11		
Missing data	3		
Comorbidity			
Other health conditions			
Units: Subjects			

No	68		
Yes	129		
Missing data	2		

BMI			
Body Mass Index (kg/m2)			
Units: kg/m2			
arithmetic mean			
standard deviation	-		
Pain NRS			
How severe is hip pain today (0-10 scale; 0=no pain at all, 10=worst pain imaginable)			
Units: 0-10 scale			
arithmetic mean			
standard deviation	-		
WOMAC - Total			
Western Ontario and McMaster Universities Arthritis Index (WOMAC) - Total scale score (0-96 scale; 0=no prolems; 96=extreme problems)			
Units: 0-96 scale			
arithmetic mean			
standard deviation	-		
WOMAC-P			
Western Ontario and McMaster Universities Arthritis Index (WOMAC) - Pain subscale score (0-20 scale; 0=no pain, 20=extreme pain)			
Units: 0-20 scale			
arithmetic mean			
standard deviation	-		
WOMAC-S			
Western Ontario and McMaster Universities Arthritis Index (WOMAC) - Stiffness subscale score (0-8 scale; 0=no stiffness, 8=extreme stiffness)			
Units: 0-8 scale			
arithmetic mean			
standard deviation	-		
WOMAC-F			
Western Ontario and McMaster Universities Arthritis Index (WOMAC) - Function subscale (0-68; 0=no difficulty; 68=extreme difficulty)			
Units: 0-68 scale			
arithmetic mean			
standard deviation	-		
PSEQ			
Pain Self-Efficacy Questionnaire (0-60 scale; 0=no confidence; 60=highest confidence)			
Units: 0-60 scale			
arithmetic mean			
standard deviation	-		
IPQ			
modified brief Illness Perceptions Questionnaire (0-50 scale; 0=full understanding, 50=least understanding)			
Units: 0-50 scale			
arithmetic mean			
standard deviation	-		
IPQ-Consequences			
modified brief Illness Perceptions Questionnaire - Consequences subscale (0-10 scale; 0=no affect at all; 10=severely affects life)			
Units: 0-10 scale			
arithmetic mean			

standard deviation	-		
IPQ-Timeline			
modified brief Illness Perceptions Questionnaire - Timeline subscale (0-10 scale; 0=last very short time; 10=last forever)			
Units: 0-10 scale arithmetic mean standard deviation	- 		
IPQ-Personal control			
modified brief Illness Perceptions Questionnaire - Personal control subscale (0-10 scale; 0=no control; 10=extreme control)			
Units: 0-10 scale arithmetic mean standard deviation	- 		
IPQ-Treatment control			
modified brief Illness Perceptions Questionnaire - Treatment control subscale (0-10 scale; 0=treatment no help; 10=treatment extremely helpful)			
Units: 0-10 scale arithmetic mean standard deviation	- 		
IPQ-Emotional response			
modified brief Illness Perceptions Questionnaire - Emotional response subscale (0-10 scale; 0=not affected emotionally; 10=extremely affected emotionally)			
Units: 0-10 scale arithmetic mean standard deviation	- 		
EQ5D			
EuroQoL EQ5D (health utilit) (-0.59 to 1.00; [-0.59=worst health utility, 1.00=best health utility)			
Units: -0.59 to 1.00 arithmetic mean standard deviation	- 		
SF-12 PCS			
Short Form-12 Physical Component Scale (SF12_PCS) (0-100 scale; 0=worst physical health, 100=best physical health)			
Units: 0-100 arithmetic mean standard deviation	- 		
SF12-MCS			
Short Form-12 Mental Component Scale (SF12_MCS) (0-100 scale; 0=worst mental health, 100=best mental health)			
Units: 0-100 scale arithmetic mean standard deviation	- 		
GAD-7			
Generalised Anxiety Disorder Assessment (7-item scale)			
Units: 0-21 scale arithmetic mean standard deviation	- 		
PHQ-8			
Patient Health Questionnaire depression scale			
Units: 0-24 scale arithmetic mean standard deviation	- 		
SPS			
Stanford Presenteeism Scale (6-30 scale; 6=minimum ability, 30=maximum ability)			

Units: score arithmetic mean standard deviation	- 		
Work Performance			
Work Performance (Numerical Rating Scale (NRS), 0-10; 0=Not at all affected, 10=Pain so bad that unable to do job). Question worded: On average to what extent has your hip problem affected your performance at work in the last 6 weeks?			
Units: score arithmetic mean standard deviation	- 		

Subject analysis sets

Subject analysis set title	Primary endpoint
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Primary endpoint = average NRS-pain score over 2 weeks, 2 months, 4 months and 6 months follow up

Reporting group values	Primary endpoint		
Number of subjects	194		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	109		
From 65-84 years	82		
85 years and over	3		
Age continuous Units: years			
arithmetic mean	63.0		
standard deviation	± 9.8		
Gender categorical Units: Subjects			
Female	110		
Male	84		
Centre Units: Subjects			
Haywood	159		
Cannock	35		
Ethnic group			
Ethnic group question: Which group do you consider yourself to belong to? White Non-white = Black/African/Carribean/Black British or Asian/Asian British or Mixed/multiple ethnic groups or Other			
Units: Subjects			
Non-white	1		
White	193		

Living alone Units: Subjects			
No	164		
Yes	30		
Currently employed Units: Subjects			
No	25		
No, retired	81		
Yes	85		
Missing data	3		
Smoking status Units: Subjects			
Never	95		
Previous	67		
Current	32		
Alcohol consumption Units: Subjects			
Daily / most days	31		
Once or twice a week	77		
Once or twice a month	35		
Once or twice a year	24		
Never	27		
Hip(s) affected			
Over the last 12 months, pain in which hip(s)			
Units: Subjects			
Both	48		
Right only	88		
Left only	58		
Duration of symptoms			
Over the last 12 months, how many days had pain			
Units: Subjects			
Less than 3 months	6		
Between 3 months and 6 months	16		
Between 6 months and 1 year	41		
More than 1 year	130		
Missing data	1		
Days of pain in last 12 months			
Over last 12 months, how many days in pain			
Units: Subjects			
Less than 7 days	1		
1-4 weeks	0		
More than 1 month but less than 3 months	12		
3 months or more	181		
Previous hip injury			
Ever injured hip badly enough to see a doctor about it			
Units: Subjects			
No	169		
Right hip only	10		
Left hip only	10		
Both hips	5		
Missing data	0		

Sleep problems			
During past 4 weeks, troubled by pain from hip in bed at night			
Units: Subjects			
No nights	9		
Only 1 or 2 nights	10		
Some nights	38		
Most nights	61		
Every night	76		
Previous hip injection			
Ever had steroid injection(s) into hip(s)?			
Units: Subjects			
No	187		
Yes	7		
Injection to other joint			
Ever had a steroid injection into a joint other than the hip			
Units: Subjects			
No	128		
Yes	65		
Missing data	1		
Preference			
Treatment preference			
Units: Subjects			
To have a hip injection	180		
Not to have a hip injection	11		
Missing data	3		
Comorbidity			
Other health conditions			
Units: Subjects			
No	67		
Yes	125		
Missing data	2		
BMI			
Body Mass Index (kg/m2)			
Units: kg/m2			
arithmetic mean	29.3		
standard deviation	± 5.7		
Pain NRS			
How severe is hip pain today (0-10 scale; 0=no pain at all, 10=worst pain imaginable)			
Units: 0-10 scale			
arithmetic mean	5.7		
standard deviation	± 2.1		
WOMAC - Total			
Western Ontario and McMaster Universities Arthritis Index (WOMAC) - Total scale score (0-96 scale; 0=no prolems; 96=extreme problems)			
Units: 0-96 scale			
arithmetic mean	50.8		
standard deviation	± 16.0		
WOMAC-P			
Western Ontario and McMaster Universities Arthritis Index (WOMAC) - Pain subscale score (0-20 scale; 0=no pain, 20=extreme pain)			
Units: 0-20 scale			
arithmetic mean	10.7		

standard deviation	± 3.3		
WOMAC-S			
Western Ontario and McMaster Universities Arthritis Index (WOMAC) - Stiffness subscale score (0-8 scale; 0=no stiffness, 8=extreme stiffness)			
Units: 0-8 scale			
arithmetic mean	4.5		
standard deviation	± 1.5		
WOMAC-F			
Western Ontario and McMaster Universities Arthritis Index (WOMAC) - Function subscale (0-68; 0=no difficulty; 68=extreme difficulty)			
Units: 0-68 scale			
arithmetic mean	35.6		
standard deviation	± 12.3		
PSEQ			
Pain Self-Efficacy Questionnaire (0-60 scale; 0=no confidence; 60=highest confidence)			
Units: 0-60 scale			
arithmetic mean	37.1		
standard deviation	± 13.7		
IPQ			
modified brief Illness Perceptions Questionnaire (0-50 scale; 0=full understanding, 50=least understanding)			
Units: 0-50 scale			
arithmetic mean	30.0		
standard deviation	± 6.7		
IPQ-Consequences			
modified brief Illness Perceptions Questionnaire - Consequences subscale (0-10 scale; 0=no affect at all; 10=severely affects life)			
Units: 0-10 scale			
arithmetic mean	6.5		
standard deviation	± 2.1		
IPQ-Timeline			
modified brief Illness Perceptions Questionnaire - Timeline subscale (0-10 scale; 0=last very short time; 10=last forever)			
Units: 0-10 scale			
arithmetic mean	9.0		
standard deviation	± 1.5		
IPQ-Personal control			
modified brief Illness Perceptions Questionnaire - Personal control subscale (0-10 scale; 0=no control; 10=extreme control)			
Units: 0-10 scale			
arithmetic mean	4.0		
standard deviation	± 2.8		
IPQ-Treatment control			
modified brief Illness Perceptions Questionnaire - Treatment control subscale (0-10 scale; 0=treatment no help; 10=treatment extremely helpful)			
Units: 0-10 scale			
arithmetic mean	7.4		
standard deviation	± 2.0		
IPQ-Emotional response			
modified brief Illness Perceptions Questionnaire - Emotional response subscale (0-10 scale; 0=not affected emotionally; 10=extremely affected emotionally)			
Units: 0-10 scale			
arithmetic mean	5.9		
standard deviation	± 2.8		

EQ5D			
EuroQoL EQ5D (health utilit) (-0.59 to 1.00; [-0.59=worst health utility, 1.00=best health utility)			
Units: -0.59 to 1.00			
arithmetic mean	0.49		
standard deviation	± 0.23		
SF-12 PCS			
Short Form-12 Physical Component Scale (SF12_PCS) (0-100 scale; 0=worst physical health, 100=best physical health)			
Units: 0-100			
arithmetic mean	34.0		
standard deviation	± 8.8		
SF12-MCS			
Short Form-12 Mental Component Scale (SF12_MCS) (0-100 scale; 0=worst mental health, 100=best mental health)			
Units: 0-100 scale			
arithmetic mean	51.3		
standard deviation	± 11.8		
GAD-7			
Generalised Anxiety Disorder Assessment (7-item scale)			
Units: 0-21 scale			
arithmetic mean	5.7		
standard deviation	± 5.9		
PHQ-8			
Patient Health Questionnaire depression scale			
Units: 0-24 scale			
arithmetic mean	6.6		
standard deviation	± 6.0		
SPS			
Stanford Presenteeism Scale (6-30 scale; 6=minimum ability, 30=maximum ability)			
Units: score			
arithmetic mean	20.2		
standard deviation	± 4.9		
Work Performance			
Work Performance (Numerical Rating Scale (NRS), 0-10; 0=Not at all affected, 10=Pain so bad that unable to do job). Question worded: On average to what extent has your hip problem affected your performance at work in the last 6 weeks?			
Units: score			
arithmetic mean	4.6		
standard deviation	± 2.8		

End points

End points reporting groups

Reporting group title	Best Current Treatment
Reporting group description:	
BCT comprised written information (Arthritis Research UK Osteoarthritis leaflet and a bespoke leaflet on exercise and functional activities), personalised advice and information about weight loss, exercise, footwear, walking aids and optimising pain management, delivered within the clinic visit.	
Reporting group title	BCT+US-L
Reporting group description:	
Best Current Treatment (BCT) combined with an ultra-sound guided injection (USGI) of 5ml 1% lidocaine only.	
Reporting group title	BCT+US-T
Reporting group description:	
Best Current Treatment (BCT) combined with an ultra-sound guided injection (USGI) of 40mg triamcinolone acetonide and 4ml 1% lidocaine hydrochloride.	
Subject analysis set title	Primary endpoint
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Primary endpoint = average NRS-pain score over 2 weeks, 2 months, 4 months and 6 months follow up	

Primary: Pain score at 2 weeks

End point title	Pain score at 2 weeks
End point description:	
Comparison of pain scores at 2 weeks follow up (0-10 pain scale; 0=no pain, 10=maximum pain)	
End point type	Primary
End point timeframe:	
2 weeks	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	Primary endpoint
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	62	63	64	189
Units: score				
arithmetic mean (standard deviation)	6.0 (± 2.3)	4.0 (± 2.4)	3.0 (± 2.5)	4.3 (± 2.7)

Statistical analyses

Statistical analysis title	Pain score (2 weeks) - BCT+US-T versus BCT
Statistical analysis description:	
Pain score at 2 weeks follow up (BCT+US-T minus BCT) adjusted for age, gender and baseline pain score	
Comparison groups	Best Current Treatment v BCT+US-T

Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-3.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.06
upper limit	-2.28
Variability estimate	Standard error of the mean

Statistical analysis title	Pain score (2 weeks) - BCT+US-T versus BCT+US-L
Statistical analysis description:	
Pain score at 2 weeks follow up (BCT+US-T minus BCT+US-L) adjusted for age, gender and baseline pain score	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	127
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.023
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	-0.14
Variability estimate	Standard error of the mean

Primary: Pain score at 2 months	
End point title	Pain score at 2 months
End point description:	
Pain score at 2 months follow up	
End point type	Primary
End point timeframe:	
2 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	Primary endpoint
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	58	65	64	187
Units: score				
arithmetic mean (standard deviation)	5.8 (± 2.5)	4.7 (± 2.6)	4.2 (± 2.8)	4.9 (± 2.7)

Statistical analyses

Statistical analysis title	Pain score (2 months) - BCT+US-T versus BCT
Statistical analysis description:	
Pain score at 2 monthsfollow up (BCT+US-T minus BCT) adjusted for age, gender and baseline pain score	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.71
upper limit	-0.92
Variability estimate	Standard error of the mean

Statistical analysis title	Pain score (2 months) - BCT+US-T versus BCT+US-L
Statistical analysis description:	
Pain score at 2 months follow up (BCT+US-T minus BCT+US-L) adjusted for age, gender and baseline pain score	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.136
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.54
upper limit	0.21
Variability estimate	Standard error of the mean

Primary: Pain score at 4 months	
End point title	Pain score at 4 months
End point description: Pain score at 4 months follow up	
End point type	Primary
End point timeframe: 4 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	Primary endpoint
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	57	63	59	179
Units: score				
arithmetic mean (standard deviation)	5.4 (± 2.9)	5.0 (± 2.6)	4.5 (± 2.7)	4.9 (± 2.7)

Statistical analyses

Statistical analysis title	Pain score (4 months) - BCT+US-T versus BCT
Statistical analysis description: Pain score at 4 months follow up (BCT+US-T minus BCT) adjusted for age, gender and baseline pain score	
Comparison groups	BCT+US-T v Best Current Treatment
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.063
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.78
upper limit	0.05
Variability estimate	Standard error of the mean

Statistical analysis title	Pain score (4 months) - BCT+US-T versus BCT+US-L
Statistical analysis description: Pain score at 4 months follow up (BCT+US-T minus BCT+US-L) adjusted for age, gender and baseline pain score	
Comparison groups	BCT+US-L v BCT+US-T

Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.291
Method	Mixed models analysis
Parameter estimate	Mean difference (net)
Point estimate	-0.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.37
upper limit	0.41
Variability estimate	Standard error of the mean

Primary: Pain score at 6 months

End point title	Pain score at 6 months

End point description:

End point type	Primary

End point timeframe:

6 months

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	Primary endpoint
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	56	61	61	178
Units: score				
arithmetic mean (standard deviation)	5.0 (± 2.8)	5.0 (± 2.5)	5.1 (± 2.7)	5.1 (± 2.7)

Statistical analyses

Statistical analysis title	Pain score (6 months) - BCT+US-T versus BCT

Statistical analysis description:

Pain score at 6 months follow up (BCT+US-T minus BCT) adjusted for age, gender and baseline pain score

Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.797
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.12

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.8
upper limit	1.04
Variability estimate	Standard error of the mean

Statistical analysis title	Pain score (6 months) - BCT+US-T versus BCT+US-L

Statistical analysis description:

Pain score at 6 months follow up (BCT+US-T minus BCT+US-L) adjusted for age, gender and baseline pain score

Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.823
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.79
upper limit	1
Variability estimate	Standard error of the mean

Primary: Pain score - overall, primary endpoint

End point title	Pain score - overall, primary endpoint

End point description:

Primary endpoint (based on all follow up pain scores)

End point type	Primary

End point timeframe:

Overall (all follow up scores: 2 weeks, 2 months, 4 months, 6 months)

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	Primary endpoint
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	63	65	66	733
Units: score				
arithmetic mean (standard deviation)	5.6 (± 2.7)	4.7 (± 2.6)	4.2 (± 2.8)	4.8 (± 2.7)

Statistical analyses

Statistical analysis title	Pain score (overall) - BCT+US-T versus BCT
Statistical analysis description:	
Pain score for all available follow up data [primary endpoint] - BCT+US-T minus BCT (adjusted for age, gender and baseline pain score)	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.15
upper limit	-0.72
Variability estimate	Standard error of the mean

Statistical analysis title	Pain score (overall) - BCT+US-T versus BCT+US-L
Statistical analysis description:	
Pain score for all available follow up data [primary endpoint] BCT+US-T minus BCT+US-L (adjusted for age, gender and baseline pain score)	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	131
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.148
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.21
upper limit	0.18
Variability estimate	Standard error of the mean

Secondary: WOMAC-Total at 2 months

End point title	WOMAC-Total at 2 months
End point description:	
Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC-Total) 0-96 [0=Minimum problems, 96=maximum problems]	
End point type	Secondary
End point timeframe:	
2 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	55	62	61	
Units: score				
arithmetic mean (standard deviation)	50.3 (± 21.1)	41.4 (± 19.2)	34.2 (± 20.3)	

Statistical analyses

Statistical analysis title	WOMAC-Total at 2 months
Statistical analysis description:	
WOMAC-Total at 2 months (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline WOMAC-Total	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-14.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.9
upper limit	-8.64
Variability estimate	Standard error of the mean

Statistical analysis title	WOMAC-Total at 2 months
Statistical analysis description:	
WOMAC-Total at 2 months (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline WOMAC-Total	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	123
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.027
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-6.68

Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.6
upper limit	-0.76
Variability estimate	Standard error of the mean

Secondary: WOMAC-Total at 4 months

End point title	WOMAC-Total at 4 months
End point description:	
Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC-Total) 0-96 [0=Minimum problems, 96=maximum problems]	
End point type	Secondary
End point timeframe:	
4 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	51	56	59	
Units: score				
arithmetic mean (standard deviation)	43.6 (± 23.1)	43.9 (± 18.5)	38.3 (± 20.7)	

Statistical analyses

Statistical analysis title	WOMAC-Total at 4 months
Statistical analysis description:	
WOMAC-Total at 4 months (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline WOMAC-Total	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	110
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.043
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-6.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.5
upper limit	-0.21
Variability estimate	Standard error of the mean

Statistical analysis title	WOMAC-Total at 4 months
Statistical analysis description:	
WOMAC-Total at 2 months (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline WOMAC-Total	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.035
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-6.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.4
upper limit	-0.45
Variability estimate	Standard error of the mean

Secondary: WOMAC-Total at 6 months	
End point title	WOMAC-Total at 6 months
End point description:	
Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC-Total) 0-96 [0=Minimum problems, 96=maximum problems]	
End point type	Secondary
End point timeframe:	
6 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	53	59	55	
Units: score				
arithmetic mean (standard deviation)	42.9 (± 22.6)	44.0 (± 19.4)	41.8 (± 20.8)	

Statistical analyses

Statistical analysis title	WOMAC-Total at 6 months
Statistical analysis description:	
WOMAC-Total at 6 months (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline WOMAC-Total	

Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	108
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.657
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.68
upper limit	4.84
Variability estimate	Standard error of the mean

Statistical analysis title	WOMAC-Total (6 months) - BCT+US-T versus BCT+US-L
Statistical analysis description:	
WOMAC-Total at 6 months (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline WOMAC-Total	
Comparison groups	BCT+US-T v BCT+US-L
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.801
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.82
upper limit	5.27
Variability estimate	Standard error of the mean

Secondary: WOMAC-Total - Overall	
End point title	WOMAC-Total - Overall
End point description:	
Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC-Total) 0-96 [0=Minimum problems, 96=maximum problems]	
End point type	Secondary
End point timeframe:	
Overall (all follow up scores: 2 months, 4 months, 6 months)	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	60	65	64	
Units: score				
arithmetic mean (standard deviation)	45.7 (± 22.4)	43.0 (± 19.0)	38.0 (± 20.7)	

Statistical analyses

Statistical analysis title	WOMAC-Total - Overall
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-7.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13
upper limit	-2.04
Variability estimate	Standard error of the mean

Statistical analysis title	WOMAC-Total - Overall
Comparison groups	BCT+US-T v BCT+US-L
Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.087
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-4.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.91
upper limit	0.67
Variability estimate	Standard error of the mean

Secondary: PSEQ at 2 months	
End point title	PSEQ at 2 months

End point description:	
Pain Self-Efficacy Questionnaire (PSEQ), 0-60 [0=No confidence; 60=Highest confidence]	
End point type	Secondary
End point timeframe:	
2 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	55	63	62	
Units: score				
arithmetic mean (standard deviation)	34.3 (± 15.9)	39.2 (± 13.6)	44.4 (± 14.2)	

Statistical analyses

Statistical analysis title	PSEQ at 2 months
Statistical analysis description:	
PSEQ at 2 months (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline PSEQ	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	9.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.1
upper limit	13.4
Variability estimate	Standard error of the mean

Statistical analysis title	PSEQ at 2 months
Statistical analysis description:	
PSEQ at 2 months (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline PSEQ	
Comparison groups	BCT+US-L v BCT+US-T

Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	6.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.15
upper limit	10.2
Variability estimate	Standard error of the mean

Secondary: PSEQ at 4 months

End point title	PSEQ at 4 months
End point description:	
Pain Self-Efficacy Questionnaire (PSEQ), 0-60 [0=No confidence; 60=Highest confidence]	
End point type	Secondary
End point timeframe:	
4 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	52	59	60	
Units: score				
arithmetic mean (standard deviation)	35.2 (± 16.7)	37.9 (± 13.2)	41.2 (± 15.0)	

Statistical analyses

Statistical analysis title	PSEQ at 4 months
Statistical analysis description:	
PSEQ at 4 months (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline PSEQ	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	6.71

Confidence interval	
level	95 %
sides	2-sided
lower limit	2.51
upper limit	10.9
Variability estimate	Standard error of the mean

Statistical analysis title	PSEQ at 4 months
Statistical analysis description:	
PSEQ at 4 months (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline PSEQ	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.011
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	5.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.21
upper limit	9.34
Variability estimate	Standard error of the mean

Secondary: PSEQ at 6 months	
End point title	PSEQ at 6 months
End point description:	
Pain Self-Efficacy Questionnaire (PSEQ), 0-60 [0=No confidence; 60=Highest confidence]	
End point type	Secondary
End point timeframe:	
6 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	53	59	58	
Units: score				
arithmetic mean (standard deviation)	37.8 (± 14.7)	36.9 (± 12.8)	38.8 (± 15.1)	

Statistical analyses

Statistical analysis title	PSEQ at 6 months
Statistical analysis description:	
PSEQ at 6 months (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline PSEQ	
Comparison groups	BCT+US-T v Best Current Treatment
Number of subjects included in analysis	111
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.452
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	1.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.62
upper limit	5.9
Variability estimate	Standard error of the mean

Statistical analysis title	PSEQ at 6 months
Statistical analysis description:	
PSEQ at 6 months (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline PSEQ	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.171
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	2.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.24
upper limit	7
Variability estimate	Standard error of the mean

Secondary: PSEQ - Overall	
End point title	PSEQ - Overall
End point description:	
Pain Self-Efficacy Questionnaire (PSEQ), 0-60 [0=No confidence; 60=Highest confidence]	
End point type	Secondary
End point timeframe:	
Overall (all follow up scores: 2 months, 4 months, 6 months)	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	60	65	65	
Units: score				
arithmetic mean (standard deviation)	35.7 (± 15.7)	38.0 (± 13.2)	41.5 (± 14.9)	

Statistical analyses

Statistical analysis title	PSEQ - Overall
Statistical analysis description:	
PSEQ overall (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline PSEQ	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	5.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.3
upper limit	9.45
Variability estimate	Standard error of the mean

Statistical analysis title	PSEQ - Overall
Statistical analysis description:	
PSEQ at 6 months (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline PSEQ	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	130
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	4.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.32
upper limit	8.23

Variability estimate	Standard error of the mean

Secondary: IPQ at 2 months	
End point title	IPQ at 2 months
End point description:	
modified brief Illness Perceptions Questionnaire (IPQ), 0-50 [0=Full understanding, 50=Least understanding]	
End point type	Secondary
End point timeframe:	
2 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	51	60	60	
Units: score				
arithmetic mean (standard deviation)	33.0 (± 9.2)	30.0 (± 8.6)	27.2 (± 10.6)	

Statistical analyses

Statistical analysis title	IPQ at 2 months
Statistical analysis description:	
IPQ at 2 months (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline IPQ	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	111
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-6.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.23
upper limit	-2.84
Variability estimate	Standard error of the mean

Statistical analysis title	IPQ at 2 months
Statistical analysis description:	
IPQ at 2 months (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline IPQ	
Comparison groups	BCT+US-L v BCT+US-T

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.073
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-2.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.59
upper limit	0.48
Variability estimate	Standard error of the mean

Secondary: IPQ at 6 months

End point title	IPQ at 6 months
End point description:	
modified brief Illness Perceptions Questionnaire (IPQ), 0-50 [0=Full understanding, 50=Least understanding]	
End point type	Secondary
End point timeframe:	
6 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	58	53	
Units: score				
arithmetic mean (standard deviation)	30.1 (± 9.2)	29.2 (± 9.5)	30.0 (± 9.0)	

Statistical analyses

Statistical analysis title	IPQ at 6 months
Statistical analysis description:	
IPQ at 6 months (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline IPQ	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.701
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.15

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.44
upper limit	3.14
Variability estimate	Standard error of the mean

Statistical analysis title	IPQ at 6 months

Statistical analysis description:

IPQ at 6 months (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline IPQ

Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	111
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.912
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.33
upper limit	3.91
Variability estimate	Standard error of the mean

Secondary: IPQ - Overall

End point title	IPQ - Overall

End point description:

modified brief Illness Perceptions Questionnaire (IPQ), 0-50 [0=Full understanding, 50=Least understanding]

End point type	Secondary

End point timeframe:

Overall (all follow up scores: 2 months, 6 months)

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	58	65	63	
Units: score				
arithmetic mean (standard deviation)	31.6 (± 9.27)	29.6 (± 9.04)	28.5 (± 9.94)	

Statistical analyses

Statistical analysis title	IPQ - Overall
Statistical analysis description:	
IPQ overall (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline IPQ	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	121
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.032
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-3.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.92
upper limit	-0.27
Variability estimate	Standard error of the mean

Statistical analysis title	IPQ - Overall
Statistical analysis description:	
IPQ overall (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline IPQ	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.326
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.57
upper limit	1.8
Variability estimate	Standard error of the mean

Secondary: SF-PCS at 2 months

End point title	SF-PCS at 2 months
End point description:	
Short Form-12 Physical Component Scale (SF12-PCS) 0-100 [0=Worst physical health, 100=Best physical health]	
End point type	Secondary
End point timeframe:	
2 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	55	60	59	
Units: score				
arithmetic mean (standard deviation)	32.8 (± 8.0)	35.0 (± 9.5)	39.1 (± 9.8)	

Statistical analyses

Statistical analysis title	SF_PCS at 2 months
Statistical analysis description:	
SF_PCS at 2 months (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline SF_PCS	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	5.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.38
upper limit	8.21
Variability estimate	Standard error of the mean

Statistical analysis title	SF-PCS at 2 months
Statistical analysis description:	
SF_PCS at 2 months (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline SF_PCS	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	4.05

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.2
upper limit	6.89
Variability estimate	Standard error of the mean

Secondary: SF-PCS at 4 months

End point title	SF-PCS at 4 months

End point description:

Short Form-12 Physical Component Scale (SF12-PCS) 0-100 [0=Worst physical health, 100=Best physical health]

End point type	Secondary

End point timeframe:

4 months

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	53	53	58	
Units: score				
arithmetic mean (standard deviation)	35.7 (± 10.8)	33.7 (± 9.7)	39.0 (± 10.6)	

Statistical analyses

Statistical analysis title	SF-PCS at 4 months

Statistical analysis description:

SF_PCS at 4 months (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline SF_PCS

Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	111
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.041
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	3.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.13
upper limit	6.01
Variability estimate	Standard error of the mean

Statistical analysis title	SF-PCS at 4 months
Statistical analysis description:	
SF_PCS at 4 months (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline SF_PCS	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	111
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	5.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.41
upper limit	8.21
Variability estimate	Standard error of the mean

Secondary: SF-PCS at 6 months	
End point title	SF-PCS at 6 months
End point description:	
Short Form-12 Physical Component Scale (SF12-PCS) 0-100 [0=Worst physical health, 100=Best physical health]	
End point type	Secondary
End point timeframe:	
6 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	50	54	51	
Units: score				
arithmetic mean (standard deviation)	33.7 (± 9.9)	34.0 (± 9.5)	37.7 (± 10.1)	

Statistical analyses

Statistical analysis title	SF-PCS at 6 months
Statistical analysis description:	
SF_PCS at 6 months (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline SF_PCS	

Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.05
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	3.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	6.08
Variability estimate	Standard error of the mean

Statistical analysis title	SF-PCS at 6 months

Statistical analysis description:

SF_PCS at 6 months (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline SF_PCS

Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	105
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.155
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	2.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.81
upper limit	5.11
Variability estimate	Standard error of the mean

Secondary: SF-PCS - Overall

End point title	SF-PCS - Overall

End point description:

Short Form-12 Physical Component Scale (SF12-PCS) 0-100 [0=Worst physical health, 100=Best physical health]

End point type	Secondary

End point timeframe:

Overall (all follow up scores: 2 months, 4 months, 6 months)

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	60	64	64	
Units: score				
arithmetic mean (standard deviation)	34.1 (± 9.6)	34.2 (± 9.6)	38.7 (± 10.1)	

Statistical analyses

Statistical analysis title	SF-PCS - Overall
Statistical analysis description:	
SF_PCS overall (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline SF_PCS	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	3.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.33
upper limit	6.27
Variability estimate	Standard error of the mean

Statistical analysis title	SF-PCS - Overall
Statistical analysis description:	
SF_PCS at 2 months (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline SF_PCS	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	3.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.43
upper limit	6.24
Variability estimate	Standard error of the mean

Secondary: SF-MCS at 2 months	
End point title	SF-MCS at 2 months
End point description:	
Short Form-12 Mental Component Scale (SF12-MCS) 0-100 [0=Worst mental health, 100=Best mental health]	
End point type	Secondary
End point timeframe:	
2 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	55	60	59	
Units: score				
arithmetic mean (standard deviation)	47.5 (± 12.9)	50.1 (± 12.3)	50.2 (± 12.0)	

Statistical analyses

Statistical analysis title	SF-MCS at 2 months
Statistical analysis description:	
SF_MCS at 2 months (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline SF_MCS	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.572
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	1.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.69
upper limit	4.87
Variability estimate	Standard error of the mean

Statistical analysis title	SF-MCS at 2 months
Statistical analysis description:	
SF_MCS at 2 months (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline SF_MCS	

Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.575
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.73
upper limit	2.63
Variability estimate	Standard error of the mean

Secondary: SF-MCS at 4 months

End point title	SF-MCS at 4 months
End point description:	
Short Form-12 Mental Component Scale (SF12-MCS) 0-100 [0=Worst mental health, 100=Best mental health]	
End point type	Secondary
End point timeframe:	
4 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	53	53	58	
Units: score				
arithmetic mean (standard deviation)	46.3 (± 13.5)	49.9 (± 11.8)	49.4 (± 12.4)	

Statistical analyses

Statistical analysis title	SF-MCS at 4 months
Statistical analysis description:	
SF_MCS at 4 months (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline SF_MCS	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	111
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.301
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	2.01

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.8
upper limit	5.83
Variability estimate	Standard error of the mean

Statistical analysis title	SF-MCS at 4 months
Statistical analysis description:	
SF_MCS at 4 months (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline SF_MCS	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	111
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.865
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.44
upper limit	4.1
Variability estimate	Standard error of the mean

Secondary: SF-MCS at 6 months	
End point title	SF-MCS at 6 months
End point description:	
Short Form-12 Mental Component Scale (SF12-MCS) 0-100 [0=Worst mental health, 100=Best mental health]	
End point type	Secondary
End point timeframe:	
6 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	50	54	51	
Units: score				
arithmetic mean (standard deviation)	49.8 (± 12.7)	49.2 (± 12.2)	48.7 (± 11.9)	

Statistical analyses

Statistical analysis title	SF-MCS at 6 months
Statistical analysis description:	
SF_MCS at 6 months (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline SF_MCS	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.195
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-2.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.61
upper limit	1.35
Variability estimate	Standard error of the mean

Statistical analysis title	SF-MCS at 6 months
Statistical analysis description:	
SF_MCS at 6 months (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline SF_MCS	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	105
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.37
upper limit	3.37
Variability estimate	Standard error of the mean

Secondary: SF-MCS - Overall

End point title	SF-MCS - Overall
End point description:	
Short Form-12 Mental Component Scale (SF12-MCS) 0-100 [0=Worst mental health, 100=Best mental health]	
End point type	Secondary

End point timeframe:
Overall (all follow up scores: 2 months, 4 months, 6 months)

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	60	64	64	
Units: score				
arithmetic mean (standard deviation)	47.8 (± 13.0)	49.8 (± 12.0)	49.5 (± 12.0)	

Statistical analyses

Statistical analysis title	SF-MCS - Overall
Statistical analysis description:	
SF_MCS overall (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline SF_MCS	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.918
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.83
upper limit	3.15
Variability estimate	Standard error of the mean

Statistical analysis title	SF-MCS - Overall
Statistical analysis description:	
SF_MCS overall (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline SF_MCS	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.843
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.29

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.6
upper limit	3.19
Variability estimate	Standard error of the mean

Secondary: EQ5D at 2 weeks

End point title	EQ5D at 2 weeks
End point description:	
EuroQol EQ5D (utility) -0.59 – 1.00 [-0.59=Worst health utility, 1.00=Best health utility]	
End point type	Secondary
End point timeframe:	
2 weeks	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	61	64	63	
Units: score				
arithmetic mean (standard deviation)	0.47 (± 0.27)	0.59 (± 0.22)	0.64 (± 0.23)	

Statistical analyses

Statistical analysis title	EQ5D at 2 weeks
Statistical analysis description:	
EQ5D at 2 weeks (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline EQ5D	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.12
upper limit	0.24
Variability estimate	Standard error of the mean

Statistical analysis title	EQ5D at 2 weeks
Statistical analysis description:	
EQ5D at 2 weeks (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline EQ5D	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	127
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.053
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0.12
Variability estimate	Standard error of the mean

Secondary: EQ5D at 2 months

End point title	EQ5D at 2 months
End point description:	
EuroQol EQ5D (utility) -0.59 – 1.00 [-0.59=Worst health utility, 1.00=Best health utility]	
End point type	Secondary
End point timeframe:	
2 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	64	62	
Units: score				
arithmetic mean (standard deviation)	0.44 (± 0.29)	0.52 (± 0.24)	0.60 (± 0.26)	

Statistical analyses

Statistical analysis title	EQ5D at 2 months
Statistical analysis description:	
EQ5D at 2 months (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline EQ5D	
Comparison groups	Best Current Treatment v BCT+US-T

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.08
upper limit	0.22
Variability estimate	Standard error of the mean

Statistical analysis title	EQ5D at 2 months
Statistical analysis description:	
EQ5D at 2 months (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline EQ5D	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.042
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0.14
Variability estimate	Standard error of the mean

Secondary: EQ5D at 4 months	
End point title	EQ5D at 4 months
End point description:	
EuroQol EQ5D (utility) -0.59 – 1.00 [-0.59=Worst health utility, 1.00=Best health utility]	
End point type	Secondary
End point timeframe:	
4 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	62	58	
Units: score				
arithmetic mean (standard deviation)	0.48 (± 0.28)	0.48 (± 0.28)	0.59 (± 0.23)	

Statistical analyses

Statistical analysis title	EQ5D at 4 months
Statistical analysis description:	
EQ5D at 4 months (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline EQ5D	
Comparison groups	BCT+US-T v Best Current Treatment
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.04
upper limit	0.19
Variability estimate	Standard error of the mean

Statistical analysis title	EQ5D at 4 months
Statistical analysis description:	
EQ5D at 4 months (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline EQ5D	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.03
upper limit	0.18
Variability estimate	Standard error of the mean

Secondary: EQ5D at 6 months	
End point title	EQ5D at 6 months
End point description: EuroQol EQ5D (utility) -0.59 – 1.00 [-0.59=Worst health utility, 1.00=Best health utility]	
End point type	Secondary
End point timeframe: 6 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	54	60	57	
Units: score				
arithmetic mean (standard deviation)	0.52 (± 0.25)	0.50 (± 0.24)	0.50 (± 0.25)	

Statistical analyses

Statistical analysis title	EQ5D at 6 months
Statistical analysis description: EQ5D at 6 months (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline EQ5D	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	111
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.889
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.07
upper limit	0.08
Variability estimate	Standard error of the mean

Statistical analysis title	EQ5D at 6 months
Statistical analysis description: EQ5D at 6 months (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline EQ5D	
Comparison groups	BCT+US-L v BCT+US-T

Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.914
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.07
upper limit	0.08
Variability estimate	Standard error of the mean

Secondary: EQ5D - Overall

End point title	EQ5D - Overall

End point description:

EuroQol EQ5D (utility) -0.59 – 1.00 [-0.59=Worst health utility, 1.00=Best health utility]

End point type	Secondary

End point timeframe:

Overall (all follow up scores: 2 weeks, 2 months, 4 months, 6 months)

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63	65	66	
Units: score				
arithmetic mean (standard deviation)	0.48 (± 0.27)	0.52 (± 0.25)	0.58 (± 0.25)	

Statistical analyses

Statistical analysis title	EQ5D - Overall

Statistical analysis description:

EQ5D overall (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline EQ5D

Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.11

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.06
upper limit	0.17
Variability estimate	Standard error of the mean

Statistical analysis title	EQ5D - Overall
Statistical analysis description:	
EQ5D overall (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline EQ5D	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	131
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.034
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.01
upper limit	0.11
Variability estimate	Standard error of the mean

Secondary: SPS at 2 months	
End point title	SPS at 2 months
End point description:	
Stanford Presenteeism Scale (SPS) 6-30 [6=Minimum ability, 30=Maximum ability]	
End point type	Secondary
End point timeframe:	
2 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	22	27	35	
Units: scale				
arithmetic mean (standard deviation)	20.0 (± 6.0)	20.1 (± 6.0)	23.4 (± 4.4)	

Statistical analyses

Statistical analysis title	SPS at 2 months
Statistical analysis description: SPS at 2 months (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline SPS	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	57
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	4.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.75
upper limit	6.38
Variability estimate	Standard error of the mean

Statistical analysis title	SPS at 2 months
Statistical analysis description: SPS at 2 months (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline SPS	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	3.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.22
upper limit	5.59
Variability estimate	Standard error of the mean

Secondary: SPS at 6 months	
End point title	SPS at 6 months
End point description: Stanford Presenteeism Scale (SPS) 6-30 [6=Minimum ability, 30=Maximum ability]	
End point type	Secondary
End point timeframe: 6 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	21	26	32	
Units: score				
arithmetic mean (standard deviation)	19.9 (± 6.6)	20.0 (± 4.7)	21.8 (± 5.1)	

Statistical analyses

Statistical analysis title	SPS at 6 months
Statistical analysis description: SPS at 6 months (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline SPS	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	53
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.073
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	2.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	4.53
Variability estimate	Standard error of the mean

Statistical analysis title	SPS at 6 months
Statistical analysis description: SPS at 6 months (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline SPS	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.031
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	2.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.22
upper limit	4.69

Variability estimate	Standard error of the mean

Secondary: SPS - Overall

End point title	SPS - Overall

End point description:

Stanford Presenteeism Scale (SPS) 6-30 [6=Minimum ability, 30=Maximum ability]

End point type	Secondary

End point timeframe:

Overall (all follow up scores: 2 months, 6 months)

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	25	30	37	
Units: score				
arithmetic mean (standard deviation)	19.9 (± 6.2)	20.1 (± 5.4)	22.7 (± 4.8)	

Statistical analyses

Statistical analysis title	SPS - Overall

Statistical analysis description:

SPS overall (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline SPS

Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	3.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.05
upper limit	5.18
Variability estimate	Standard error of the mean

Statistical analysis title	SPS - Overall

Statistical analysis description:

SPS overall (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline SPS

Comparison groups	BCT+US-L v BCT+US-T

Number of subjects included in analysis	67
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	2.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.98
upper limit	4.88
Variability estimate	Standard error of the mean

Secondary: Work performance at 2 months

End point title	Work performance at 2 months

End point description:

Work Performance 0-10 numerical integer scale [0=Not at all affected, 10=Pain is so bad unable to do job]
Question worded: On average to what extent has your hip pain affected your performance at work in the last 2 months since your clinical visit?

End point type	Secondary

End point timeframe:

2 months

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	21	28	36	
Units: score				
arithmetic mean (standard deviation)	4.1 (± 3.0)	4.9 (± 3.0)	3.1 (± 2.4)	

Statistical analyses

Statistical analysis title	Work performance at 2 months

Statistical analysis description:

WP at 2 months (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline WP

Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	57
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.72

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.93
upper limit	-0.51
Variability estimate	Standard error of the mean

Statistical analysis title	Work performance at 2 months
Statistical analysis description:	
WP at 2 months (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline WP	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	64
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.011
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.64
upper limit	-0.34
Variability estimate	Standard error of the mean

Secondary: Work performance at 6 months

End point title	Work performance at 6 months
End point description:	
Work Performance 0-10 numerical integer scale [0=Not at all affected, 10=Pain is so bad unable to do job] Question worded: On average to what extent has your hip pain affected your performance at work in the last 6 months since your clinical visit?	
End point type	Secondary
End point timeframe:	
6 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	21	26	32	
Units: score				
arithmetic mean (standard deviation)	4.4 (± 3.2)	4.5 (± 2.7)	4.2 (± 2.7)	

Statistical analyses

Statistical analysis title	Work performance at 6 months
Statistical analysis description: WP at 6 months (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline WP	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	53
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.182
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.08
upper limit	0.39
Variability estimate	Standard error of the mean

Statistical analysis title	Work performance at 6 months
Statistical analysis description: WP at 6 months (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline WP	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.435
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.64
upper limit	0.71
Variability estimate	Standard error of the mean

Secondary: Work performance - Overall

End point title	Work performance - Overall

End point description:

Work Performance 0-10 numerical integer scale [0=Not at all affected, 10=Pain is so bad unable to do job]

End point type	Secondary

End point timeframe:

Overall (all follow up scores: 2 months, 6 months)

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	24	30	38	
Units: score				
arithmetic mean (standard deviation)	4.3 (± 3.1)	4.7 (± 2.8)	3.6 (± 2.6)	

Statistical analyses

Statistical analysis title	Work performance - Overall

Statistical analysis description:

WP overall (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline WP

Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.023
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.39
upper limit	-0.18
Variability estimate	Standard error of the mean

Statistical analysis title	Work performance - Overall

Statistical analysis description:

WP overall (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline WP

Comparison groups	BCT+US-L v BCT+US-T

Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.067
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.03
upper limit	0.07
Variability estimate	Standard error of the mean

Secondary: Perceived change at 2 weeks

End point title	Perceived change at 2 weeks

End point description:

Perceived change at 2 weeks (6-point ordered categorical scale: completely better, much better, somewhat better, same, somewhat worse, much worse)
Question worded: Compared to 2 weeks ago when you attended your hospital clinic appointment for your hip problem, how would you rate your hip problem now?

End point type	Secondary

End point timeframe:

2 weeks

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	62	64	64	
Units: participants				
completely better	0	1	2	
much better	0	15	34	
somewhat better	7	20	14	
same	39	23	10	
somewhat worse	10	4	4	
much worse	6	1	0	

Statistical analyses

Statistical analysis title	Perceived change at 2 weeks

Statistical analysis description:

Perceived change (specifically for this analysis (due to zero cell counts) dichotomsed as: completely better/much better/somewhat better and same/somewhat worse/much worse.
Comparison BCT+US-T v BCT (reference) adjusted for age, gender and baseline pain.

Comparison groups	Best Current Treatment v BCT+US-T

Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	6.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.39
upper limit	14.2
Variability estimate	Standard error of the mean

Statistical analysis title	Perceived change at 2 weeks

Statistical analysis description:

Perceived change (for analysis dichotomsed as: completely better/much better and somewhat better/same/somewhat worse/much worse).
Comparison BCT+US-T v BCT+US-L (reference) adjusted for age, gender and baseline pain.

Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.009
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	2.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.42
upper limit	3.66
Variability estimate	Standard error of the mean

Secondary: Perceived change at 2 months

End point title	Perceived change at 2 months

End point description:

Perceived change at 2 months (6-point ordered categorical scale: completely better, much better, somewhat better, same, somewhat worse, much worse)
Question worded: Compared to 2 months ago when you attended your hospital clinic appointment for your hip problem, how would you rate your hip problem now?

End point type	Secondary

End point timeframe:

2 months

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	58	65	66	
Units: participants				
completely better	1	0	2	
much better	3	11	28	
somewhat better	6	21	9	
same	27	19	14	
somewhat worse	16	12	9	
much worse	5	2	4	

Statistical analyses

Statistical analysis title	Perceived change at 2 months

Statistical analysis description:

Perceived change (dichotomsed as completely better/much better and somewhat better/same/somewhat worse/much worse).
Comparison BCT+US-T v BCT (reference) adjusted for age, gender and baseline pain.

Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	6.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.48
upper limit	17.9
Variability estimate	Standard error of the mean

Statistical analysis title	Perceived change at 2 months

Statistical analysis description:

Perceived improvement: completely better/much better & somewhat better/same/somewhat worse/much worse
Comparison BCT+US-T v BCT+US-L (reference) adjusted for age, gender and baseline pain.

Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	2.63

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.43
upper limit	4.82
Variability estimate	Standard error of the mean

Secondary: Perceived change at 4 months

End point title	Perceived change at 4 months

End point description:

Perceived change at 4 months (6-point ordered categorical scale: completely better, much better, somewhat better, same, somewhat worse, much worse)
Question worded: Compared to 4 months ago when you attended your hospital clinic appointment for your hip problem, how would you rate your hip problem now?

End point type	Secondary

End point timeframe:

4 months

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	57	63	60	
Units: participants				
completely better	0	0	1	
much better	10	9	15	
somewhat better	5	10	15	
same	17	24	14	
somewhat worse	16	14	13	
much worse	9	6	2	

Statistical analyses

Statistical analysis title	Perceived change at 4 months

Statistical analysis description:

Perceived change (for analysis dichotomsed: as completely better/much better and somewhat better/same/somewhat worse/much worse).
Comparison BCT+US-T v BCT (reference) adjusted for age, gender and baseline pain.

Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.234
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.54

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	3.11
Variability estimate	Standard error of the mean

Statistical analysis title	Perceived change at 4 months

Statistical analysis description:

Perceived change (for analysis dichotomsed: as completely better/much better and somewhat better/same/somewhat worse/much worse).
Comparison BCT+US-T v BCT+US-L (reference) adjusted for age, gender and baseline pain.

Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	123
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.105
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	3.88
Variability estimate	Standard error of the mean

Secondary: Perceived change at 6 months

End point title	Perceived change at 6 months

End point description:

Perceived change at 6 months (6-point ordered categorical scale: completely better, much better, somewhat better, same, somewhat worse, much worse)
Question worded: Compared to 6 months ago when you attended your hospital clinic appointment for your hip problem, how would you rate your hip problem now?

End point type	Secondary

End point timeframe:

6 months

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	61	61	
Units: participants				
completely better	2	0	1	
much better	10	11	13	

somewhat better	7	12	13	
same	14	18	13	
somewhat worse	14	15	18	
much worse	9	5	3	

Statistical analyses

Statistical analysis title	Perceived change at 6 months
Statistical analysis description:	
Perceived change (for analysis dichotomsed: as completely better/much better and somewhat better/same/somewhat worse/much worse). Comparison BCT+US-T v BCT (reference) adjusted for age, gender and baseline pain.	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.794
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.55
upper limit	2.17
Variability estimate	Standard error of the mean

Statistical analysis title	Perceived change at 6 months
Statistical analysis description:	
Perceived change (for analysis dichotomsed: as completely better/much better and somewhat better/same/somewhat worse/much worse). Comparison BCT+US-T v BCT+US-L (reference) adjusted for age, gender and baseline pain.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.516
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	2.58
Variability estimate	Standard error of the mean

Secondary: Sleep difficulty at 2 months

End point title	Sleep difficulty at 2 months

End point description:

Nights with sleep difficulty during past 4 weeks (5-point ordered categorical scale: no nights, only 1 or 2 nights, some nights, most nights, every night)

End point type	Secondary

End point timeframe:

2 months

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	55	62	63	
Units: participants				
no nights	4	7	12	
1-2 nights	5	5	16	
some nights	17	19	15	
most nights	15	17	12	
every night	14	14	8	

Statistical analyses

Statistical analysis title	Sleep difficulty at 2 months

Statistical analysis description:

For analysis categories were dichotomised as: no nights/1-2 nights/ some nights & most nights/every night.
Comparison BCT+US-T v BCT (reference) adjusted for age, gender, baseline pain and baseline sleep.

Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.28
upper limit	3.03
Variability estimate	Standard error of the mean

Statistical analysis title	Sleep difficulty at 2 months
Statistical analysis description:	
For analysis categories were dichotomised as: no nights/1-2 nights/ some nights & most nights/every night. Comparison BCT+US-T v BCT+US-L (reference) adjusted for age, gender, baseline pain and baseline sleep.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.013
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.12
upper limit	2.63
Variability estimate	Standard error of the mean

Secondary: Sleep difficulty at 4 months	
End point title	Sleep difficulty at 4 months
End point description:	
Nights with sleep difficulty during past 4 weeks (5-point ordered categorical scale: no nights, only 1 or 2 nights, some nights, most nights, every night)	
End point type	Secondary
End point timeframe:	
4 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	54	61	59	
Units: participants				
no nights	8	6	9	
1-2 nights	9	9	13	
some nights	16	12	15	
most nights	13	25	14	
every night	8	11	8	

Statistical analyses

Statistical analysis title	Sleep difficulty at 4 months

Statistical analysis description:

For analysis categories were dichotomised as: no nights/1-2 nights/ some nights & most nights/every night.
Comparison BCT+US-T v BCT (reference) adjusted for age, gender, baseline pain and baseline sleep.

Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	113
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.314
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	2.04
Variability estimate	Standard error of the mean

Statistical analysis title	Sleep difficulty at 4 months

Statistical analysis description:

For analysis categories were dichotomised as: no nights/1-2 nights/ some nights & most nights/every night.
Comparison BCT+US-T v BCT+US-L (reference) adjusted for age, gender, baseline pain and baseline sleep.

Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.022
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.06
upper limit	2.27
Variability estimate	Standard error of the mean

Secondary: Sleep difficulty at 6 months

End point title	Sleep difficulty at 6 months

End point description:

Nights with sleep difficulty during past 4 weeks (5-point ordered categorical scale: no nights, only 1 or 2 nights, some nights, most nights, every night)

End point type	Secondary
End point timeframe: 6 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	52	60	57	
Units: participants				
no nights	9	7	8	
1-2 nights	6	5	5	
some nights	15	16	14	
most nights	15	21	15	
every night	7	11	15	

Statistical analyses

Statistical analysis title	Sleep difficulty at 6 months
Statistical analysis description: For analysis categories were dichotomised as: no nights/1-2 nights/ some nights & most nights/every night. Comparison BCT+US-T v BCT (reference) adjusted for age, gender, baseline pain and baseline sleep.	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.799
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1.61
Variability estimate	Standard error of the mean

Statistical analysis title	Sleep difficulty at 6 months
Statistical analysis description: For analysis categories were dichotomised as: no nights/1-2 nights/ some nights & most nights/every night. Comparison BCT+US-T v BCT+US-L (reference) adjusted for age, gender, baseline pain and baseline sleep.	
Comparison groups	BCT+US-L v BCT+US-T

Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.586
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.52
Variability estimate	Standard error of the mean

Secondary: Satisfaction with care received at 2 months

End point title	Satisfaction with care received at 2 months

End point description:

Question worded: How satisfied are you with the care you have received for your hip problem in the last 2 months?
Response options on 5-point ordered categorical scale: very satisfied, quite satisfied, no opinion, not very satisfied, not at all satisfied

End point type	Secondary

End point timeframe:

2 months

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	51	62	57	
Units: participants				
very satisfied	6	14	27	
quite satisfied	13	14	14	
no opinion	15	22	9	
not very satisfied	10	7	5	
not at all satisfied	7	5	2	

Statistical analyses

Statistical analysis title	Satisfaction with care received at 2 months

Statistical analysis description:

For analysis dichtomisation was as follows: very satisfied/quite satisfied & no opinion/not very satisfied/ not at all satisfied.
Comparison BCT+US-T v BCT (reference) adjusted for age, gender and baseline pain.

Comparison groups	Best Current Treatment v BCT+US-T

Number of subjects included in analysis	108
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.33
upper limit	2.93
Variability estimate	Standard error of the mean

Statistical analysis title	Satisfaction with care received at 2 months

Statistical analysis description:

For analysis dichtomisation was as follows: very satisfied/quite satisfied & no opinion/not very satisfied/ not at all satisfied.
Comparison BCT+US-T v BCT+US-L (reference) adjusted for age, gender and baseline pain.

Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.17
upper limit	2.21
Variability estimate	Standard error of the mean

Secondary: Satisfaction with care received at 6 months

End point title	Satisfaction with care received at 6 months

End point description:

Question worded: How satisfied are you with the care you have received for your hip problem in the last 4 months?
Response options on 5-point ordered categorical scale: very satisfied, quite satisfied, no opinion, not very satisfied, not at all satisfied

End point type	Secondary

End point timeframe:

6 months

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	52	57	55	
Units: participants				
very satisfied	6	17	15	
quite satisfied	12	19	17	
no opinion	20	15	12	
not very satisfied	10	6	7	
not at all satisfied	4	0	4	

Statistical analyses

Statistical analysis title	Satisfaction with care received at 6 months

Statistical analysis description:

For analysis dichtomisation was as follows: very satisfied/quite satisfied & no opinion/not very satisfied/ not at all satisfied.
Comparison BCT+US-T v BCT (reference) adjusted for age, gender and baseline pain.

Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.016
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.11
upper limit	2.66
Variability estimate	Standard error of the mean

Statistical analysis title	Satisfaction with care received at 6 months

Statistical analysis description:

For analysis dichtomisation was as follows: very satisfied/quite satisfied & no opinion/not very satisfied/ not at all satisfied.
Comparison BCT+US-T v BCT+US-L (reference) adjusted for age, gender and baseline pain.

Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.63
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	0.93

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1.25
Variability estimate	Standard error of the mean

Secondary: Rating of overall results of care at 2 months

End point title	Rating of overall results of care at 2 months
End point description:	
Question worded: How would you rate the overall results of the care for your hip problem? (0-10 scale; 0=terrible, 10=excellent)	
End point type	Secondary
End point timeframe:	
2 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	50	61	57	
Units: score				
arithmetic mean (standard deviation)	4.7 (± 3.3)	5.8 (± 3.3)	7.2 (± 2.6)	

Statistical analyses

Statistical analysis title	Rating of overall results of care at 2 months
Statistical analysis description:	
Mean difference for BCT+US-T minus BCT adjusted for age, gender and baseline pain.	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	2.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.4
upper limit	3.61
Variability estimate	Standard error of the mean

Statistical analysis title	Rating of overall results of care at 2 months
Statistical analysis description: Mean difference for BCT+US-T minus BCT+US-L adjusted for age, gender and baseline pain.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.008
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	1.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	2.47
Variability estimate	Standard error of the mean

Secondary: Rating of overall results of care at 6 months	
End point title	Rating of overall results of care at 6 months
End point description: Question worded: How would you rate the overall results of the care for your hip problem? (0-10 scale; 0=terrible, 10=excellent)	
End point type	Secondary
End point timeframe: 6 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	51	58	55	
Units: score				
arithmetic mean (standard deviation)	5.0 (± 2.9)	6.6 (± 2.7)	6.6 (± 2.8)	

Statistical analyses

Statistical analysis title	Rating of overall results of care at 6 months
Statistical analysis description: Mean difference for BCT+US-T minus BCT adjusted for age, gender and baseline pain.	
Comparison groups	Best Current Treatment v BCT+US-T

Number of subjects included in analysis	106
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	2.71
Variability estimate	Standard error of the mean

Statistical analysis title	Rating of overall results of care at 6 months
Statistical analysis description:	
Mean difference for BCT+US-T minus BCT+US-L adjusted for age, gender and baseline pain.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	113
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.784
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.91
upper limit	1.21
Variability estimate	Standard error of the mean

Secondary: Expectation for pain relief at 2 months

End point title	Expectation for pain relief at 2 months
End point description:	
Question worded as: To what extent do you feel your expectations for pain relief have been met? Response options on 4-point ordered categorical scale: definitely not met, not met, no opinion, probably met	
End point type	Secondary
End point timeframe:	
2 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	53	62	57	
Units: participants				
probably met	15	22	32	
no opinion	11	13	8	
not met	20	19	12	
definitely not met	7	8	5	

Statistical analyses

Statistical analysis title	Expectations for pain relief at 2 months
Statistical analysis description:	
For analysis dichotomisation was as follows: probably met/no opinion & not met/definitely not met. Comparison BCT+US-T v BCT (reference) adjusted for age, gender and baseline pain.	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	110
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.01
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.1
upper limit	2.1
Variability estimate	Standard error of the mean

Statistical analysis title	Expectations for pain relief at 2 months
Statistical analysis description:	
For analysis dichotomisation was as follows: probably met/no opinion & not met/definitely not met. Comparison BCT+US-T v BCT+US-L (reference) adjusted for age, gender and baseline pain.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.105
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.95
upper limit	1.67

Variability estimate	Standard error of the mean

Secondary: Expectation for pain relief at 6 months

End point title	Expectation for pain relief at 6 months

End point description:

Question worded as: To what extent do you feel your expectations for pain relief have been met? Response options on 4-point ordered categorical scale: definitely not met, not met, no opinion, probably met

End point type	Secondary

End point timeframe:

6 months

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	51	59	57	
Units: participants				
probably met	17	22	25	
no opinion	10	9	13	
not met	15	20	13	
definitely not met	9	8	6	

Statistical analyses

Statistical analysis title	Expectation for pain relief at 6 months

Statistical analysis description:

For analysis dichotomisation was as follows: probably met/no opinion & not met/definitely not met. Comparison BCT+US-T v BCT (reference) adjusted for age, gender and baseline pain.

Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	108
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.059
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.99
upper limit	1.84
Variability estimate	Standard error of the mean

Statistical analysis title	Expectations for pain relief at 6 months

Statistical analysis description:

For analysis dichotomisation was as follows: probably met/no opinion & not met/definitely not met. Comparison BCT+US-T v BCT+US-L (reference) adjusted for age, gender and baseline pain.

Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.098
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.95
upper limit	1.73
Variability estimate	Standard error of the mean

Secondary: Same care again for hip problem at 2 months

End point title	Same care again for hip problem at 2 months

End point description:

Question worded: Would you have the same care again if you had the same condition?
Ordered 5-point categorical response options: definitely not, probably not, no opinion, probably, definitely

End point type	Secondary

End point timeframe:

2 months

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	51	61	58	
Units: participants				
definitely	4	16	26	
probably	11	14	15	
no opinion	16	14	11	
probably not	12	11	4	
definitely not	8	6	2	

Statistical analyses

Statistical analysis title	Same care again at 2 months

Statistical analysis description:

Final analysis categories dichotomised as: definitely/probably & no opinion/probably not/definitely not.

Comparison BCT+US-T v BCT (reference) adjusted for age, gender and baseline pain.

Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	2.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.53
upper limit	3.8
Variability estimate	Standard error of the mean

Statistical analysis title	Same care again at 2 months

Statistical analysis description:

Final analysis categories dichotomised as: definitely/probably & no opinion/probably not/definitely not.
Comparison BCT+US-T v BCT+US-L (reference) adjusted for age, gender and baseline pain.

Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.016
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.07
upper limit	1.96
Variability estimate	Standard error of the mean

Secondary: Same care again for hip problem at 6 months

End point title	Same care again for hip problem at 6 months

End point description:

Question worded: Would you have the same care again if you had the same condition?
Ordered 5-point categorical response options: definitely not, probably not, no opinion, probably, definitely

End point type	Secondary

End point timeframe:

6 months

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	58	54	
Units: participants				
definitely	6	17	18	
probably	11	19	17	
no opinion	20	10	10	
probably not	7	7	5	
definitely not	5	5	4	

Statistical analyses

Statistical analysis title	Same care again at 6 months
Statistical analysis description:	
Final analysis categories dichotomised as: definitely/probably & no opinion/probably not/definitely not. Comparison BCT+US-T v BCT (reference) adjusted for age, gender and baseline pain.	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.22
upper limit	2.92
Variability estimate	Standard error of the mean

Statistical analysis title	Same care again at 6 months
Statistical analysis description:	
Final analysis categories dichotomised as: definitely/probably & no opinion/probably not/definitely not. Comparison BCT+US-T v BCT+US-L (reference) adjusted for age, gender and baseline pain.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.687
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.06

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.4
Variability estimate	Standard error of the mean

Secondary: Satisfaction with information received at 2 months

End point title	Satisfaction with information received at 2 months

End point description:

Question worded: How satisfied are you with the information you received concerning your hip problem? 5-point ordered categorical response options: very satisfied, quite satisfied, no opinion, not very satisfied, not at all satisfied

End point type	Secondary

End point timeframe:

2 months

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	61	62	
Units: participants				
very satisfied	15	28	35	
quite satisfied	23	20	21	
no opinion	5	5	1	
not very satisfied	6	7	3	
not at all satisfied	7	1	2	

Statistical analyses

Statistical analysis title	Satisfaction with information received at 2 months

Statistical analysis description:

Final analysis category dichotomisation: very satisfied/quite satisfied & no opinion/not very satisfied/not at all satisfied.
Comparison BCT+US-T v BCT (reference) adjusted for age, gender and baseline pain.

Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.35

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.1
upper limit	1.64
Variability estimate	Standard error of the mean

Statistical analysis title	Satisfaction with information received at 2 months

Statistical analysis description:

Final analysis category dichotomisation: very satisfied/quite satisfied & no opinion/not very satisfied/not at all satisfied.
Comparison BCT+US-T v BCT+US-L (reference) adjusted for age, gender and baseline pain.

Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	123
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.07
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.99
upper limit	1.34
Variability estimate	Standard error of the mean

Secondary: Satisfaction with information received at 6 months

End point title	Satisfaction with information received at 6 months

End point description:

Question worded: How satisfied are you with the information you received concerning your hip problem? 5-point ordered categorical response options: very satisfied, quite satisfied, no opinion, not very satisfied, not at all satisfied

End point type	Secondary

End point timeframe:

6 months

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	52	60	58	
Units: participants				
very satisfied	12	29	23	
quite satisfied	20	21	19	
no opinion	8	6	8	

not very satisfied	9	4	6	
not at all satisfied	3	0	2	

Statistical analyses

Statistical analysis title	Satisfaction with information received at 6 months

Statistical analysis description:

Final analysis category dichotomisation: very satisfied/quite satisfied & no opinion/not very satisfied/not at all satisfied.
Comparison BCT+US-T v BCT (reference) adjusted for age, gender and baseline pain.

Comparison groups	BCT+US-T v Best Current Treatment
Number of subjects included in analysis	110
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.209
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.56
Variability estimate	Standard error of the mean

Statistical analysis title	Satisfaction with information received at 6 months

Statistical analysis description:

Final analysis category dichotomisation: very satisfied/quite satisfied & no opinion/not very satisfied/not at all satisfied.
Comparison BCT+US-T v BCT+US-L (reference) adjusted for age, gender and baseline pain.

Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.174
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.94
upper limit	1.4
Variability estimate	Standard error of the mean

Secondary: Understanding of hip problem at 2 months	
End point title	Understanding of hip problem at 2 months
End point description: Question worded as: How well do you understand your hip problem? 4-point categorical response options of: very clearly, quite clearly, no opinion, not very clearly	
End point type	Secondary
End point timeframe: 2 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	62	62	
Units: participants				
very clearly	19	29	25	
quite clearly	29	24	29	
no opinion	2	5	1	
not very clearly	6	4	7	

Statistical analyses

Statistical analysis title	Understanding hip problem at 2 months
Statistical analysis description: Final analysis categories dichotomised as: very clearly/quite clearly & no opinion/not very clearly. Comparison BCT+US-T v BCT (reference) adjusted for age, gender and baseline pain.	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.884
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.17
Variability estimate	Standard error of the mean

Statistical analysis title	Understanding of hip problem at 2 months

Statistical analysis description:

Final analysis categories dichotomised as: very clearly/quite clearly & no opinion/not very clearly.
Comparison BCT+US-T v BCT+US-L (reference) adjusted for age, gender and baseline pain.

Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.797
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.17
Variability estimate	Standard error of the mean

Secondary: Understanding of hip problem at 6 months

End point title	Understanding of hip problem at 6 months

End point description:

Question worded as: How well do you understand your hip problem?
4-point categorical response options of: very clearly, quite clearly, no opinion, not very clearly

End point type	Secondary

End point timeframe:

6 months

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	52	60	58	
Units: participants				
very clearly	18	24	22	
quite clearly	24	30	24	
no opinion	5	1	5	
not very clearly	5	5	7	

Statistical analyses

Statistical analysis title	Understanding of hip problem at 6 months

Statistical analysis description:

Final analysis categories dichotomised as: very clearly/quite clearly & no opinion/not very clearly.
Comparison BCT+US-T v BCT (reference) adjusted for age, gender and baseline pain.

Comparison groups	BCT+US-T v Best Current Treatment

Number of subjects included in analysis	110
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.813
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.18
Variability estimate	Standard error of the mean

Statistical analysis title	Understanding of hip problem at 6 months
Statistical analysis description:	
Comparison BCT+US-T v BCT+US-L (reference) adjusted for age, gender and baseline pain.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.104
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.03
Variability estimate	Standard error of the mean

Secondary: Still have questions at 2 months	
End point title	Still have questions at 2 months
End point description:	
Question worded as: Do you still have questions about your hip problem? (yes/no)	
End point type	Secondary
End point timeframe:	
2 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	55	61	61	
Units: participants				
no	30	33	37	
yes	25	28	24	

Statistical analyses

Statistical analysis title	Still have questions at 2 months
Statistical analysis description: Comparison BCT+US-T v BCT (reference) adjusted for age, gender and baseline pain.	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.446
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.82
Variability estimate	Standard error of the mean

Statistical analysis title	Still have questions at 2 months
Statistical analysis description: Comparison BCT+US-T v BCT+US-L (reference) adjusted for age, gender and baseline pain.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.486
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.75
Variability estimate	Standard error of the mean

Secondary: Still have questions at 6 months	
End point title	Still have questions at 6 months
End point description: Question worded as: Do you still have questions about your hip problem? (yes/no)	
End point type	Secondary
End point timeframe: 6 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	52	60	57	
Units: participants				
no	27	26	28	
yes	25	34	29	

Statistical analyses

Statistical analysis title	Still have questions at 6 months
Statistical analysis description: Comparison BCT+US-T v BCT (reference) adjusted for age, gender and baseline pain.	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.844
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	1.43
Variability estimate	Standard error of the mean

Statistical analysis title	Still have questions at 6 months
Statistical analysis description: Comparison BCT+US-T v BCT+US-L (reference) adjusted for age, gender and baseline pain.	
Comparison groups	BCT+US-L v BCT+US-T

Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.481
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.61
Variability estimate	Standard error of the mean

Secondary: Kept from usual activities at 2 months

End point title	Kept from usual activities at 2 months

End point description:

Question worded: Have you been kept from your usual activities (e.g. work, hobbies, housework) at any time in the last 2 months because of hip pain? (yes/no)

End point type	Secondary

End point timeframe:

2 months

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	62	60	
Units: participants				
no	25	32	40	
yes	31	30	20	

Statistical analyses

Statistical analysis title	Kept from usual activities at 2 months

Statistical analysis description:

Comparison BCT+US-T v BCT (reference) adjusted for age, gender and baseline pain.

Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.009
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.79

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.15
upper limit	2.7
Variability estimate	Standard error of the mean

Statistical analysis title	Kept from usual activities at 2 months
Statistical analysis description:	
Comparison BCT+US-T v BCT+US-L (reference) adjusted for age, gender and baseline pain.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.121
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	2.22
Variability estimate	Standard error of the mean

Secondary: Kept from usual activities at 6 months	
End point title	Kept from usual activities at 6 months
End point description:	
Question worded: Have you been kept from your usual activities (e.g. work, hobbies, housework) at any time in the last 4 months because of hip pain? (yes/no)	
End point type	Secondary
End point timeframe:	
6 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	53	59	55	
Units: participants				
no	25	28	27	
yes	28	31	28	

Statistical analyses

Statistical analysis title	Kept from usual activities at 6 months
Statistical analysis description: Comparison BCT+US-T v BCT (reference) adjusted for age, gender and baseline pain.	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	108
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.465
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.69
Variability estimate	Standard error of the mean

Statistical analysis title	Kept from usual activities at 6 months
Statistical analysis description: Comparison BCT+US-T v BCT+US-L (reference) adjusted for age, gender and baseline pain.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.677
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.54
Variability estimate	Standard error of the mean

Secondary: Pain score dichotomy at 2 weeks

End point title	Pain score dichotomy at 2 weeks
End point description: Evaluation of dichotomised follow up pain score (pain score <5; pain score>=5)	
End point type	Secondary
End point timeframe: 2 weeks	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	62	63	64	
Units: participants				
<5	16	32	44	
>=5	46	31	20	

Statistical analyses

Statistical analysis title	Pain >=5 at 2 weeks
Statistical analysis description:	
Pain dichotomy (0-4, 5-10). Difference (BCT+US-T minus BCT) adjusted for age, gender, baseline pain.	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	2.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.75
upper limit	4.26
Variability estimate	Standard error of the mean

Statistical analysis title	Pain >=5 at 2 weeks
Statistical analysis description:	
Pain dichotomy (0-4, 5-10). Difference (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	127
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.028
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.37

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.03
upper limit	1.82
Variability estimate	Standard error of the mean

Secondary: Pain score dichotomy at 2 months

End point title	Pain score dichotomy at 2 months
End point description:	
Evaluation of dichotomised follow up pain score (pain score <5; pain score>=5)	
End point type	Secondary
End point timeframe:	
2 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	58	65	64	
Units: participants				
<5	20	32	37	
>=5	38	33	27	

Statistical analyses

Statistical analysis title	Pain >=5 at 2 months
Statistical analysis description:	
Pain dichotomy (0-4, 5-10). Difference (BCT+US-T minus BCT) adjusted for age, gender, baseline pain.	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.16
upper limit	2.63
Variability estimate	Standard error of the mean

Statistical analysis title	Pain >=5 at 2 months
Statistical analysis description:	
Pain dichotomy (0-4, 5-10). Difference (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.279
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.65
Variability estimate	Standard error of the mean

Secondary: Pain score dichotomy at 4 months	
End point title	Pain score dichotomy at 4 months
End point description:	
Evaluation of dichotomised follow up pain score (pain score <5; pain score>=5)	
End point type	Secondary
End point timeframe:	
4 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	57	63	59	
Units: participants				
<5	19	27	31	
>=5	38	36	28	

Statistical analyses

Statistical analysis title	Pain >=5 at 4 months
Statistical analysis description:	
Pain dichotomy (0-4, 5-10). Difference (BCT+US-T minus BCT) adjusted for age, gender, baseline pain.	
Comparison groups	Best Current Treatment v BCT+US-T

Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.03
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.05
upper limit	2.52
Variability estimate	Standard error of the mean

Statistical analysis title	Pain >=5 at 4 months
Statistical analysis description:	
Pain dichotomy (0-4, 5-10). Difference (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.258
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.8
Variability estimate	Standard error of the mean

Secondary: Pain score dichotomy at 6 months	
End point title	Pain score dichotomy at 6 months
End point description:	
Evaluation of dichotomised follow up pain score (pain score <5; pain score>=5)	
End point type	Secondary
End point timeframe:	
6 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	61	61	
Units: participants				
<5	24	23	25	
>=5	32	38	36	

Statistical analyses

Statistical analysis title	Pain >=5 at 6 months
Statistical analysis description:	
Pain dichotomy (0-4, 5-10). Difference (BCT+US-T minus BCT) adjusted for age, gender, baseline pain.	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.97
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	1.5
Variability estimate	Standard error of the mean

Statistical analysis title	Pain >=5 at 6 months
Statistical analysis description:	
Pain dichotomy (0-4, 5-10). Difference (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	1.7
Variability estimate	Standard error of the mean

Secondary: WOMAC - Pain subscale at 2 months

End point title	WOMAC - Pain subscale at 2 months
End point description:	
WOMAC pain subscale (0-20; 0=no pain, 20=max pain)	
End point type	Secondary
End point timeframe:	
2 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	57	62	61	
Units: scale				
arithmetic mean (standard deviation)	10.7 (± 3.8)	8.7 (± 4.1)	7.0 (± 4.3)	

Statistical analyses

Statistical analysis title	WOMAC pain subscale at 2 months
Statistical analysis description:	
WOMAC mean pain difference (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline WOMAC pain.	
Comparison groups	BCT+US-T v Best Current Treatment
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-3.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.02
upper limit	-2.2
Variability estimate	Standard error of the mean

Statistical analysis title	WOMAC pain subscale at 2 months
Statistical analysis description:	
WOMAC mean pain difference (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline WOMAC pain.	
Comparison groups	BCT+US-L v BCT+US-T

Number of subjects included in analysis	123
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.013
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.1
upper limit	-0.37
Variability estimate	Standard error of the mean

Secondary: WOMAC - Pain subscale at 4 months

End point title	WOMAC - Pain subscale at 4 months
End point description:	
WOMAC pain subscale (0-20; 0=no pain, 20=max pain)	
End point type	Secondary
End point timeframe:	
4 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	53	59	59	
Units: scale				
arithmetic mean (standard deviation)	9.0 (± 4.6)	9.1 (± 4.1)	7.9 (± 4.3)	

Statistical analyses

Statistical analysis title	WOMAC pain subscale at 4 months
Statistical analysis description:	
WOMAC mean pain difference (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline WOMAC pain.	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.087
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.25

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.67
upper limit	0.18
Variability estimate	Standard error of the mean

Statistical analysis title	WOMAC pain subscale at 4 months
Statistical analysis description:	
WOMAC mean pain difference (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline WOMAC pain.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.079
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.62
upper limit	0.14
Variability estimate	Standard error of the mean

Secondary: WOMAC - Pain subscale at 6 months	
End point title	WOMAC - Pain subscale at 6 months
End point description:	
WOMAC pain subscale (0-20; 0=no pain, 20=max pain)	
End point type	Secondary
End point timeframe:	
6 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	53	60	56	
Units: scale				
arithmetic mean (standard deviation)	9.0 (± 4.5)	9.1 (± 4.1)	8.8 (± 4.3)	

Statistical analyses

Statistical analysis title	WOMAC pain subscale at 6 months
Statistical analysis description:	
WOMAC mean pain difference (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline WOMAC pain.	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.738
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.91
upper limit	0.97
Variability estimate	Standard error of the mean

Statistical analysis title	WOMAC pain subscale at 6 months
Statistical analysis description:	
WOMAC mean pain difference (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline WOMAC pain.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.738
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.63
upper limit	1.15
Variability estimate	Standard error of the mean

Secondary: WOMAC - Pain subscale overall

End point title	WOMAC - Pain subscale overall
End point description:	
WOMAC pain subscale (0-20; 0=no pain, 20=severe pain)	
End point type	Secondary
End point timeframe:	
Overall (all data across 2 months, 4 months, 6 months)	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	61	65	64	
Units: scale				
arithmetic mean (standard deviation)	9.6 (± 4.4)	9.0 (± 4.1)	7.9 (± 4.3)	

Statistical analyses

Statistical analysis title	WOMAC pain subscale - Overall
Statistical analysis description:	
WOMAC mean pain difference (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline WOMAC pain.	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.01
upper limit	-0.54
Variability estimate	Standard error of the mean

Statistical analysis title	WOMAC pain subscale - Overall
Statistical analysis description:	
WOMAC mean pain difference (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline WOMAC pain.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.079
Method	Mixed models analysis
Parameter estimate	Mean difference (net)
Point estimate	-1.07

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.26
upper limit	0.12
Variability estimate	Standard error of the mean

Secondary: WOMAC - Stiffness subscale at 2 months

End point title	WOMAC - Stiffness subscale at 2 months
End point description:	
WOMAC stiffness subscale (0-8; 0=no stiffness, 8=max stiffness)	
End point type	Secondary
End point timeframe:	
2 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	57	63	63	
Units: scale				
arithmetic mean (standard deviation)	4.3 (± 1.9)	3.7 (± 1.7)	3.2 (± 1.9)	

Statistical analyses

Statistical analysis title	WOMAC stiffness subscale at 2 months
Statistical analysis description:	
WOMAC mean stiffness difference (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline WOMAC stiffness.	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.87
upper limit	-0.62
Variability estimate	Standard error of the mean

Statistical analysis title	WOMAC stiffness subscale at 2 months
Statistical analysis description:	
WOMAC mean stiffness difference (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline WOMAC stiffness.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.088
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.14
upper limit	0.08
Variability estimate	Standard error of the mean

Secondary: WOMAC - Stiffness subscale at 4 months	
End point title	WOMAC - Stiffness subscale at 4 months
End point description:	
WOMAC stiffness subscale (0-8; 0=no stiffness, 8=max stiffness)	
End point type	Secondary
End point timeframe:	
4 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	53	60	60	
Units: scale				
arithmetic mean (standard deviation)	3.8 (± 1.9)	3.8 (± 1.8)	3.7 (± 1.9)	

Statistical analyses

Statistical analysis title	WOMAC stiffness subscale at 4 months
Statistical analysis description:	
WOMAC mean stiffness difference (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline WOMAC stiffness.	
Comparison groups	Best Current Treatment v BCT+US-T

Number of subjects included in analysis	113
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.445
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.89
upper limit	0.39
Variability estimate	Standard error of the mean

Statistical analysis title	WOMAC stiffness subscale at 4 months
Statistical analysis description:	
WOMAC mean stiffness difference (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline WOMAC stiffness.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.714
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.73
upper limit	0.5
Variability estimate	Standard error of the mean

Secondary: WOMAC - Stiffness subscale at 6 months	
End point title	WOMAC - Stiffness subscale at 6 months
End point description:	
WOMAC stiffness subscale (0-8; 0=no stiffness, 8=max stiffness)	
End point type	Secondary
End point timeframe:	
6 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	53	59	56	
Units: scale				
arithmetic mean (standard deviation)	3.7 (± 1.9)	3.8 (± 1.8)	3.7 (± 1.7)	

Statistical analyses

Statistical analysis title	WOMAC stiffness subscale at 6 months
Statistical analysis description:	
WOMAC mean stiffness difference (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline WOMAC stiffness.	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.866
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.75
upper limit	0.54
Variability estimate	Standard error of the mean

Statistical analysis title	WOMAC stiffness subscale at 6 months
Statistical analysis description:	
WOMAC mean stiffness difference (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline WOMAC stiffness.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.749
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.68
upper limit	0.57
Variability estimate	Standard error of the mean

Secondary: WOMAC - Stiffness subscale - Overall	
End point title	WOMAC - Stiffness subscale - Overall
End point description:	
WOMAC Stiffness subscale (0-8; 0=no stiffness, 8=max stiffness)	
End point type	Secondary
End point timeframe:	
Overall (all data across 2, 4 and 6 months)	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	61	65	65	
Units: scale				
arithmetic mean (standard deviation)	3.9 (± 1.9)	3.8 (± 1.8)	3.5 (± 1.8)	

Statistical analyses

Statistical analysis title	WOMAC stiffness subscale Overall
Statistical analysis description:	
WOMAC mean stiffness difference (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline WOMAC stiffness.	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.389
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.08
upper limit	0.01
Variability estimate	Standard error of the mean

Statistical analysis title	WOMAC stiffness subscale Overall
Statistical analysis description:	
WOMAC mean stiffness difference (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline WOMAC stiffness.	
Comparison groups	BCT+US-L v BCT+US-T

Number of subjects included in analysis	130
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.056
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.76
upper limit	0.3
Variability estimate	Standard error of the mean

Secondary: WOMAC - Function subscale at 2 months

End point title	WOMAC - Function subscale at 2 months
End point description:	
WOMAC function subscale (0-68; 0=no functional limitation, 68=max functional limitation)	
End point type	Secondary
End point timeframe:	
2 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	55	63	62	
Units: scale				
arithmetic mean (standard deviation)	35.3 (± 16.1)	29.1 (± 14.3)	23.8 (± 15.0)	

Statistical analyses

Statistical analysis title	WOMAC function subscale at 2 months
Statistical analysis description:	
WOMAC mean function subscale difference (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline WOMAC function score.	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-10.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.8
upper limit	5.95
Variability estimate	Standard error of the mean

Statistical analysis title	WOMAC function subscale at 2 months
Statistical analysis description:	
WOMAC mean function subscale difference (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline WOMAC function score.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-4.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.19
upper limit	-0.7
Variability estimate	Standard error of the mean

Secondary: WOMAC function subscale at 4 months	
End point title	WOMAC function subscale at 4 months
End point description:	
WOMAC function subscale (0-68; 0=no functional limitation, 68=max functional limitation)	
End point type	Secondary
End point timeframe:	
4 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	51	59	60	
Units: scale				
arithmetic mean (standard deviation)	30.7 (± 17.2)	31.3 (± 13.5)	26.7 (± 15.1)	

Statistical analyses

Statistical analysis title	WOMAC function subscale at 4 months
Statistical analysis description:	
WOMAC mean function subscale difference (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline WOMAC function score.	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	111
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.034
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-4.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.23
upper limit	-0.37
Variability estimate	Standard error of the mean

Statistical analysis title	WOMAC function subscale at 4 months
Statistical analysis description:	
WOMAC mean function subscale difference (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline WOMAC function score.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.025
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-4.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.16
upper limit	-0.61
Variability estimate	Standard error of the mean

Secondary: WOMAC - Function subscale at 6 months	
End point title	WOMAC - Function subscale at 6 months
End point description:	
WOMAC function subscale (0-68; 0=no functional limitation, 68=max functional limitation)	
End point type	Secondary
End point timeframe:	
6 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	53	59	57	
Units: scale				
arithmetic mean (standard deviation)	30.2 (± 16.7)	31.0 (± 14.3)	28.8 (± 15.2)	

Statistical analyses

Statistical analysis title	WOMAC function subscale at 6 months
Statistical analysis description:	
WOMAC mean function subscale difference (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline WOMAC function score.	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	110
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.587
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.74
upper limit	3.25
Variability estimate	Standard error of the mean

Statistical analysis title	WOMAC function subscale at 6 months
Statistical analysis description:	
WOMAC mean function subscale difference (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline WOMAC function score.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.666
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.96

Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.3
upper limit	3.38
Variability estimate	Standard error of the mean

Secondary: WOMAC - Function subscale Overall

End point title	WOMAC - Function subscale Overall
End point description:	
WOMAC function subscale (0-68; 0=no functional limitation, 68=max functional limitation)	
End point type	Secondary
End point timeframe:	
Overall (all data across 2, 4 and 6 months)	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	60	65	65	
Units: scale				
arithmetic mean (standard deviation)	32.1 (± 16.7)	30.4 (± 14.0)	26.4 (± 15.1)	

Statistical analyses

Statistical analysis title	WOMAC function subscale Overall
Statistical analysis description:	
WOMAC mean function subscale difference (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline WOMAC function score.	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-5.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.41
upper limit	-1.53
Variability estimate	Standard error of the mean

Statistical analysis title	WOMAC function subscale Overall
Statistical analysis description:	
WOMAC mean function subscale difference (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline WOMAC function score.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	130
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.064
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-3.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.4
upper limit	0.21
Variability estimate	Standard error of the mean

Secondary: IPQ Consequences subscale Overall	
End point title	IPQ Consequences subscale Overall
End point description:	
IPQ consequences subscale (0-10; 0=No affect at all, 10=Severly affects life)	
End point type	Secondary
End point timeframe:	
Overall (all data for 2 and 6 months)	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	59	65	65	
Units: scale				
arithmetic mean (standard deviation)	6.0 (± 2.6)	5.9 (± 2.3)	5.5 (± 2.7)	

Statistical analyses

Statistical analysis title	IPQ Consequences subscale Overall
Statistical analysis description:	
Mean subscale difference (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline IPQ subscale score.	
Comparison groups	Best Current Treatment v BCT+US-T

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.133
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.27
upper limit	0.17
Variability estimate	Standard error of the mean

Statistical analysis title	IPQ Consequences subscale Overall
Statistical analysis description:	
Mean subscale difference (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline IPQ subscale score.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	130
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.326
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.04
upper limit	0.35
Variability estimate	Standard error of the mean

Secondary: IPQ Timeline subscale Overall	
End point title	IPQ Timeline subscale Overall
End point description:	
IPQ timelines subscale (0-10; 0=Last very short time, 10=Last forever)	
End point type	Secondary
End point timeframe:	
Overall (all data across 2 and 6 months)	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	59	65	65	
Units: scale				
arithmetic mean (standard deviation)	8.7 (± 2.1)	8.4 (± 2.2)	8.7 (± 2.2)	

Statistical analyses

Statistical analysis title	IPQ Timeline subscale Overall
Statistical analysis description:	
Mean subscale difference (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline IPQ subscale score.	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.847
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.74
upper limit	0.6
Variability estimate	Standard error of the mean

Statistical analysis title	IPQ Timeline subscale Overall
Statistical analysis description:	
Mean subscale difference (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline IPQ subscale score.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	130
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.228
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.25
upper limit	1.05
Variability estimate	Standard error of the mean

Secondary: IPQ Personal control subscale	
End point title	IPQ Personal control subscale
End point description: IPQ personal control subscale (0-10; 0=No control, 10=Extreme control)	
End point type	Secondary
End point timeframe: Overall (across 2 and 6 months)	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	59	65	65	
Units: scale				
arithmetic mean (standard deviation)	4.3 (± 2.7)	4.2 (± 2.7)	4.5 (± 2.9)	

Statistical analyses

Statistical analysis title	IPQ Personal control Overall
Statistical analysis description: Mean subscale difference (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline IPQ subscale score.	
Comparison groups	BCT+US-T v Best Current Treatment
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.777
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.93
upper limit	0.69
Variability estimate	Standard error of the mean

Statistical analysis title	IPQ Personal control subscale Overall
Statistical analysis description: Mean subscale difference (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline IPQ subscale score.	
Comparison groups	BCT+US-L v BCT+US-T

Number of subjects included in analysis	130
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.519
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.52
upper limit	1.03
Variability estimate	Standard error of the mean

Secondary: IPQ Treatment control subscale Overall

End point title	IPQ Treatment control subscale Overall
End point description:	
IPQ treatment control subscale (0-10; 0=Treatment no help, 10=Treatment extremely helpful)	
End point type	Secondary
End point timeframe:	
Overall (across 2 and 6 months)	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	59	65	64	
Units: scale				
arithmetic mean (standard deviation)	3.9 (± 2.9)	5.0 (± 3.1)	6.1 (± 3.2)	

Statistical analyses

Statistical analysis title	IPQ Treatment control subscale Overall
Statistical analysis description:	
Mean subscale difference (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline IPQ subscale score.	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	123
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	2.13

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.11
upper limit	3.15
Variability estimate	Standard error of the mean

Statistical analysis title	IPQ Treatment control subscale Overall
Statistical analysis description:	
Mean subscale difference (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline IPQ subscale score.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.048
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.01
upper limit	1.95
Variability estimate	Standard error of the mean

Secondary: IPQ Emotional response subscale Overall	
End point title	IPQ Emotional response subscale Overall
End point description:	
IPQ emotional response subscale (0-10; 0=Not affected emotionally, 10=Extremely affected emotionally)	
End point type	Secondary
End point timeframe:	
Overall (all data across 2 and 6 months)	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	59	65	65	
Units: scale				
arithmetic mean (standard deviation)	5.2 (± 2.9)	4.8 (± 2.9)	4.7 (± 3.1)	

Statistical analyses

Statistical analysis title	IPQ Emotional response subscale Overall

Statistical analysis description:

Mean subscale difference (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline IPQ subscale score.

Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.116
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.43
upper limit	0.16
Variability estimate	Standard error of the mean

Statistical analysis title	IPQ Emotional response subscale Overall

Statistical analysis description:

Mean subscale difference (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline IPQ subscale score.

Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	130
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.268
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.19
upper limit	0.33
Variability estimate	Standard error of the mean

Secondary: QALYs

End point title	QALYs[1]

End point description:

Calculation of Quality-Adjusted-Life-Years by linear interpolation of EQ5D values for baseline through 2 weeks, 2 months, 4 months and 6 months (with imputation of missing EQ5D data via multiple imputation)

End point type	Secondary

End point timeframe:

Overall (Baseline through to 6 months follow up)

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: QALYs are derived from measures of EQ5D at all timepoints and hence can not be reported solely at baseline or any other time point.

End point values	Best Current Treatment	BCT+US-T		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	67	66		
Units: scale				
arithmetic mean (standard deviation)	0.218 (± 0.110)	0.264 (± 0.102)		

Statistical analyses

Statistical analysis title	QALYs

Statistical analysis description:

Mean QALYs difference (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline EQ5D score.

Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	133
Analysis specification	Pre-specified
Analysis type	superiority
Method	Regression, Linear
Parameter estimate	Mean difference (final values)
Point estimate	0.048
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.026
upper limit	0.07
Variability estimate	Standard error of the mean

Secondary: NHS costs

End point title	NHS costs[2]

End point description:

Total UK National Health Service Costs (GBP, £)

End point type	Secondary

End point timeframe:

Overall (baseline through 6 months follow up)

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: NHS costs are assessed between baseline and 6 months and were not collected at baseline.

End point values	Best Current Treatment	BCT+US-T		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	67	66		
Units: pounds (GBP)				
arithmetic mean (standard deviation)	327.45 (± 1188.68)	165.85 (± 212.71)		

Statistical analyses

Statistical analysis title	NHS cost difference
Statistical analysis description: Mean NHS cost (£) difference (BCT+US-T minus BCT)	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	133
Analysis specification	Pre-specified
Analysis type	superiority
Method	Regression, Linear
Parameter estimate	Mean difference (final values)
Point estimate	-161.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	-583.95
upper limit	54.18
Variability estimate	Standard error of the mean

Secondary: BMI at 6 months

End point title	BMI at 6 months
End point description: Body Mass Index at 6 months (kg/m2)	
End point type	Secondary
End point timeframe: 6 months	

End point values	Best Current Treatment	BCT+US-L	BCT+US-T	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	48	51	48	
Units: kg/m2				
arithmetic mean (standard deviation)	29.4 (± 6.1)	28.1 (± 4.7)	29.1 (± 5.8)	

Statistical analyses

Statistical analysis title	BMI at 6 months
Statistical analysis description:	
Mean difference (BCT+US-T minus BCT) adjusted for age, gender, baseline pain and baseline BMI.	
Comparison groups	Best Current Treatment v BCT+US-T
Number of subjects included in analysis	96
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.612
Method	Regression, Linear
Parameter estimate	Mean difference (final values)
Point estimate	-0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.85
upper limit	0.5
Variability estimate	Standard error of the mean

Statistical analysis title	BMI at 6 months
Statistical analysis description:	
Mean difference (BCT+US-T minus BCT+US-L) adjusted for age, gender, baseline pain and baseline BMI.	
Comparison groups	BCT+US-L v BCT+US-T
Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.76
Method	Regression, Linear
Parameter estimate	Mean difference (final values)
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.55
upper limit	0.75
Variability estimate	Standard error of the mean

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
6 months	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	CTCAE
Dictionary version	4.0

Reporting groups	
Reporting group title	Best Current Treatment
Reporting group description:	
BCT comprised written information (Arthritis Research UK Osteoarthritis leaflet and a bespoke leaflet on exercise and functional activities), personalised advice and information about weight loss, exercise, footwear, walking aids and optimising pain management, delivered within the clinic visit.	
Reporting group title	BCT+US-L
Reporting group description:	
Best Current Treatment (BCT) combined with an ultra-sound guided injection (USGI) of 5ml 1% lidocaine only.	
Reporting group title	BCT+US-T
Reporting group description:	
Best Current Treatment (BCT) combined with an ultra-sound guided injection (USGI) of 40mg triamcinolone acetonide and 4ml 1% lidocaine hydrochloride.	

Serious adverse events	Best Current Treatment	BCT+US-L	BCT+US-T
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 67 (2.99%)	2 / 65 (3.08%)	3 / 65 (4.62%)
number of deaths (all causes)	0	0	2
number of deaths resulting from adverse events	0	0	2
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 67 (0.00%)	0 / 65 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 67 (0.00%)	1 / 65 (1.54%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Multiple sclerosis relapse			

subjects affected / exposed	0 / 67 (0.00%)	1 / 65 (1.54%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 67 (0.00%)	0 / 65 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	1 / 67 (1.49%)	0 / 65 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteonecrosis			
subjects affected / exposed	1 / 67 (1.49%)	0 / 65 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Endocarditis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 65 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Best Current Treatment	BCT+US-L	BCT+US-T
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 67 (2.99%)	26 / 65 (40.00%)	25 / 65 (38.46%)
Injury, poisoning and procedural complications			
Bruising			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 67 (0.00%)	16 / 65 (24.62%)	15 / 65 (23.08%)
occurrences (all)	0	16	15
Fall			

subjects affected / exposed	0 / 67 (0.00%)	1 / 65 (1.54%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Flushing			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 67 (0.00%)	0 / 65 (0.00%)	4 / 65 (6.15%)
occurrences (all)	0	0	4
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 67 (0.00%)	1 / 65 (1.54%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders - Other, specify	Additional description: Restless legs		
subjects affected / exposed	0 / 67 (0.00%)	0 / 65 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Neuralgia			
subjects affected / exposed	0 / 67 (0.00%)	1 / 65 (1.54%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Paraesthesia			
subjects affected / exposed	0 / 67 (0.00%)	0 / 65 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Menorrhagia			
subjects affected / exposed	0 / 67 (0.00%)	0 / 65 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 67 (0.00%)	0 / 65 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 67 (0.00%)	0 / 65 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Skin hypopigmentation			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 67 (0.00%)	2 / 65 (3.08%)	4 / 65 (6.15%)
occurrences (all)	0	2	4
Skin atrophy			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 67 (0.00%)	2 / 65 (3.08%)	2 / 65 (3.08%)
occurrences (all)	0	2	2
Skin and subcutaneous tissue disorders - Other, specify	Additional description: Rash - non-specific		
subjects affected / exposed	0 / 67 (0.00%)	2 / 65 (3.08%)	0 / 65 (0.00%)
occurrences (all)	0	2	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 67 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences (all)	0	1	1
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: For Best Current Treatment, arthralgia during exercises. For BCT+US-L and BCT+US-T, arthralgia following injection		
alternative assessment type: Systematic			
subjects affected / exposed	2 / 67 (2.99%)	7 / 65 (10.77%)	1 / 65 (1.54%)
occurrences (all)	2	7	1
Pain in extremity	Additional description: Plantar fasciitis		
subjects affected / exposed	0 / 67 (0.00%)	0 / 65 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Infections and infestations			
Infections and infestations - Other, specify			
subjects affected / exposed	0 / 67 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences (all)	0	1	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 September 2016	1) Change to the Reference Safety Information to ensure the latest version of the summary of product characteristics (SmPC) was being used. The new SmPC listed porphyria as an additional contraindication to 1% lidocaine hydrochloride. Addition to exclusion criteria and implementation of urgent safety measure therefore implemented. 2) Due to day-to day variability of osteoarthritis symptoms, a number of potential participants did not meet the eligibility criterion of pain of 4/10 on the day of assessment. In order to address suboptimal recruitment, the inclusion criteria were amended from requiring "Moderate-to-severe hip pain (a score of four or more on a 0–10 numeric rating scale (NRS)) on the day of assessment" to Moderate-to-severe hip pain (a score of four or more on a 0–10 numeric rating scale (NRS)) on average over the last 2 weeks and current hip pain rated as at least 1 out of 10 (on a 0– 10 NRS) on the day of assessment."
18 October 2016	This amendment introduced an additional consent form to record consent to screening (eligibility assessment) by potential participants who attended having consulted with hip pain in primary care in the last 12 months and being identified by electronic search of GP practices by the local clinical research network.
06 February 2017	Following an MHRA Drug Safety Update (dated 14 December 2016) which highlighted the risk of systemic corticosteroid adverse effects when corticosteroids (including intra-articular triamcinolone) are co-administered to patients taking cobicistat and ritonavir, receiving cobicistat or ritonavir were added to the exclusion criteria via an urgent safety measure.
04 May 2018	1) Revision to required sample size. In response to under-recruitment, the Data Monitoring Committee advised us to explore the robustness of the baseline parameters used to inform the sample size calculation. The original sample size calculation was based on comparisons of participants' 'average' follow-up pain numeric rating scale (NRS) scores, based on a random effects linear repeated-measures model, with a 'cluster' size of 4 (denoting 4 follow-up assessments), postulated intra-correlation of 0.7 and baseline-outcome correlation of 0.5. 116 participants per arm (348 total) were required to detect a minimum difference of 1.5 points in mean pain NRS score (anticipated baseline standard deviation (SD) of pain scores=4.5; effect size 0.33) between BCT+US-T and BCT across the 6-month follow-up period (5% 2-tailed significance, 90% power, 15% loss to follow-up). The observed baseline SD was 1.7 (SD for follow up scores 2.5) ie lower than the expected SD of 4.5. The stipulated clinically important difference in the primary outcome of 1.5 in context of this baseline SD would be 'large' (effect size> 0.8). It was also noted that the MCID was as low as 1.0 in some studies (equating to a "moderate" effect size 0.4 with respect to SD of 2.5). Hence the revised sample size required 68 participants per arm (204 total) to detect a minimum difference of 1.0 point in mean pain NRS score (SD 2.5; effect size 0.4) between BCT+US-T and BCT alone across the 6-month follow-up period (80% power, 5% 2-tailed significance, repeated measures correlation 0.5, baseline-outcome correlation 0.2, 15% loss to follow-up). 2) Clarification of safety reporting procedures. Addition to the Participant Information Leaflet information about possible visual side-effects of triamcinolone acetonide following a MHRA drug safety update. 3) Owing to lack of capacity and funding, a secondary qualitative objective to explore reasons for non-participation was removed.

06 November 2018	Due to limited funding for long-term follow-up and linkage to the National Joint Registry, joint replacement surgery has been removed as a secondary outcome measure from the trial protocol.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

None

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/30021588