CASE REPORT FORM

Facet-joint injections for people with persistent non-specific low back pain study (FIS)

Sponsor: University of Warwick and University Hospitals Coventry and Warwickshire NHS Trust

EudraCT number: 2014-000682-50

PLEASE COMPLETE ALL CRF PAGES LEGIBLY USING A BLACK BALL-POINT PEN AND BLOCK LETTERS

VISIT A - Eligibility / Diagnostic Assessment

1. Date informed consent signed by participant :

d	d	m	o	n	y	y	y	y

2. Under which version of the protocol was consent signed:

☐ . ☐

3. Participant's current employment status (*please tick one)*:

- ☐ Full-time employed
- ☐ Part-time employed
- ☐ Self employed
- ☐ Retired/looking after home/inactive
- ☐ Unpaid work
- ☐ Unemployed
- ☐ Full time student
- ☐ Other, please specify_____

FACET INJECTION STUDY	**Facet Injection Study** Case Report Form (CRF)	
	Participant Initials:	**Site ID:** **Participant Trial ID:**

VISIT A - Eligibility / Diagnostic Assessment

INCLUSION CRITERIA

Please tick all appropriate boxes. A response of NO disqualifies the patient from participation in the study.

	Yes	No
1. Patient is able and willing to comply with the trial procedures and signed and dated informed consent is obtained.	☐	☐
2. Patient aged ≥18 with at least moderately troublesome low back pain present for at least 6 months.	☐	☐
3. Patient's low back pain is their predominant musculoskeletal pain.	☐	☐
4. Patient has undergone registered health professional therapist-delivered treatment for low back pain in the preceding two years prior to inclusion.	☐	☐
5. Patient meets clinical criteria for possible facet joint pain .*	☐	☐
6. Patient is able to manage text messaging, or paper based diary for daily data collection.	☐	☐
7. Patient is fluent in written and spoken English.	☐	☐

**Where there is no radicular symptoms (defined as pain radiating below the knee) and no sacro-iliac joint pain elicited using a pain provocation test and increased pain unilaterally, bilaterally on lumbar para-spinal palpation, and increased low back pain on one or more of the following; extension (more than flexion), rotation, extension/side flexion, extension/rotation.*

FACET INJECTION STUDY	**Facet Injection Study** Case Report Form (CRF)	
	Participant Initials:	**Site ID:** **Participant Trial ID:**

VISIT A - Eligibility / Diagnostic Assessment

EXCLUSION CRITERIA

Please tick all appropriate boxes. A tick in a shaded box disqualifies the patient from the study.

		Yes	No
1.	Patient is able to attend for randomised treatment and/ or is considered unsuitable to participate in the trial by an investigator.	☐	☐
2.	Patient is able and willing to undergo injections.	☐	☐
3.	Patient has used oral corticosteroids or had a corticosteroid injection in the past three months.	☐	☐
4.	Patient has an underlying serious psychiatric or psychological disorder.	☐	☐
5.	Patient has previously undergone spinal injections.	☐	☐
6.	Patient has previously undergone spinal surgery.	☐	☐
7.	Patient has a known contraindication* to facet joint injections.	☐	☐
8.	Patient has a known allergy to the constituents of the planned injections.	☐	☐
9.	Patient is pregnant, or suspected pregnancy.	☐	☐
10.	Patient was previously randomised in this trial.	☐	☐
11.	Patient is currently participating in another clinical trial (with an unregistered medicinal product), or less than 90 days have passed since completing participation in such a trial.	☐	☐

**For example, a serious co-morbidity (e.g. severe chronic onset pulmonary disease (COPD), poorly controlled diabetes) malignancy, infection, inflammatory disorder, or fracture or is taking anti-coagulants medications.*

Inclusion/Exclusion criteria review

Does the patient continue to meet all inclusion/exclusion criteria ?

☐ **Yes**

☐ **No** - Patient is withdrawn from the study. Please complete withdrawal CRF page and Final CRF page.

Physiotherapist/investigator undertaking eligibility/diagnostic assessment:			
Name :			
Signature :		**Date signed:**	DD – MON-YYYY

FACET INJECTION STUDY	Facet Injection Study Case Report Form (CRF)	
	Participant Initials: ☐☐☐ Site ID: ☐☐☐☐☐☐ Participant Trial ID: ☐☐☐☐	

VISIT A - Eligibility / Diagnostic Assessment

MEDICAL HISTORY—Back pain and general health

1. How long has the participant had back pain:

☐ 6 to 12 months ☐ 1 to 2 years ☐ 2 to 5 years ☐ >5 years

2. Previous back pain treatments: *(tick all that apply)*

Treatment type	Yes or No	If yes, enter date of last treatment or tick unknown
Physiotherapy	☐ Yes ☐ No	d d m o n y y y y ☐ Unknown
Osteopathy	☐ Yes ☐ No	d d m o n y y y y ☐ Unknown
Chiropractic	☐ Yes ☐ No	d d m o n y y y y ☐ Unknown
Acupuncture	☐ Yes ☐ No	d d m o n y y y y ☐ Unknown
Other, *please specify: _____	☐ Yes ☐ No	d d m o n y y y y ☐ Unknown
Other, *please specify: _____	☐ Yes ☐ No	d d m o n y y y y ☐ Unknown

3. Troublesomeness of back pain reported by participant during diagnostic assessment visit :
(tick only one)

☐ Moderately troublesome ☐ Very troublesome ☐ Extremely troublesome

Physiotherapist/investigator undertaking eligibility/diagnostic assessment:			
Name :			
Signature :		Date signed:	DD – MON-YYYY

FACET INJECTION STUDY	Facet Injection Study Case Report Form (CRF)	
	Participant Initials:	**Site ID:** **Participant Trial ID:**

VISIT A - Eligibility / Diagnostic Assessment

DIAGNOSTIC ASSESSMENT

1. Date of diagnostic assessment: d d m o n y y y y

2. Following diagnostic assessment, does the patient have the following :

Check all boxes either yes or no

Criteria For Assessment		Yes/No	
No radicular symptoms (defined as pain radiating below the knee or objective neurological signs above the knee#)		☐ Yes ☐ No	All responses must be ticked YES for the patient to fulfil the diagnostic criteria and continued inclusion in the study
No sacro-iliac joint pain elicited using pain provocations test (three or more positive)		☐ Yes ☐ No	
Increased pain unilaterally, bilaterally on lumbar para-spinal palpation		☐ Yes ☐ No	
Increased low back pain on one or more of the following		☐ Yes ☐ No	
A. Extension (more than flexion)		☐ Yes ☐ No	If No, provide reason why : .....
B. Rotation	**RIGHT SIDE** ☐ Yes ☐ No	**LEFT SIDE** ☐ Yes ☐ No	If No for either right or left side, provide reason why : .....
C. Extension/side flexion*	**RIGHT SIDE** ☐ Yes ☐ No	**LEFT SIDE** ☐ Yes ☐ No	If No for either right or left side, provide reason why : .....
D. Extension/rotation*	**RIGHT SIDE** ☐ Yes ☐ No	**LEFT SIDE** ☐ Yes ☐ No	If No for either right or left side, provide reason why : ....

* Both tests representative of regular compression patterns.

\# Using a 'contracted' neurological examination.

Physiotherapist/investigator undertaking eligibility/diagnostic assessment:			
Name :			
Signature :		**Date signed:**	DD – MON-YYYY

FACET INJECTION STUDY	**Facet Injection Study** Case Report Form (CRF)	
	Participant Initials: **Site ID:**	**Participant Trial ID:**

VISIT A - Eligibility / Diagnostic Assessment

1. **Specific causes of back pain(*)** ***(Tick all boxes either yes or no)***

Cause	Yes/No
Malignancy	☐ Yes ☐ No
Fracture	☐ Yes ☐ No
Infection	☐ Yes ☐ No
Possible ankylosing spondylitis	☐ Yes ☐ No
Cauda equina compression	☐ Yes ☐ No
Radicular pain suitable for surgery	☐ Yes ☐ No

*If any specific causes of back pain are identified during the diagnostic assessment (ticked yes), the patient is not eligible for the study.

2. **Have identified specific causes of low back pain been reported to patient's GP ?**

☐ Yes ☐ No ☐ Not Applicable

3. **Following the diagnostic assessment, if patient is not eligible for the study, has the patient signed informed consent to collect data regarding diagnostic assessment?**

☐ **Yes**– completed diagnostic assessment data to be provided to WCTU

☐ **No**– copy of diagnostic assessment data into patient's clinical records and copy to investigator file

4. **When undertaking active movements, did the patient indicate any of the following:**

i. Increased pain on rising from flexion ☐ Yes ☐ No ☐ Not Done, reason.....

ii. Symptoms best on walking ☐ Yes ☐ No ☐ Not Done, reason.....

iii. Symptoms best when sitting ☐ Yes ☐ No ☐ Not Done, reason.....

iv. Onset of pain paraspinal ☐ Yes ☐ No ☐ Not Done, reason.....

Physiotherapist/investigator undertaking eligibility/diagnostic assessment:			
Name :			
Signature :		**Date signed:**	DD – MON-YYYY

VISIT A - Eligibility / Diagnostic Assessment

CONCOMITANT MEDICIATIONS

☐ None – **OR** – complete

	Drug name (trade or generic)	Dose	Unit	Frequency	Indication	Start Date (dd-mmm-yyyy) Or tick unknown
1						___/___/___ ☐ Unknown
2						___/___/___ ☐ Unknown
3						___/___/___ ☐ Unknown
4						___/___/___ ☐ Unknown
5						___/___/___ ☐ Unknown
6						___/___/___ ☐ Unknown
7						___/___/___ ☐ Unknown
8						___/___/___ ☐ Unknown
9						___/___/___ ☐ Unknown
10						___/___/___ ☐ Unknown

If additional concomitant medications are to be recorded, please use the 'additional concomitant medications page'

1. Has the participant completed study baseline questionnaire during assessment visit ?

☐ Yes ☐ No - please specify the reason why below (tick only one):

☐ Participant removed questionnaire for completion

☐ Other, please specify reason:

.....

Physiotherapist/investigator undertaking eligibility/diagnostic assessment:			
Name :			
Signature :		**Date signed:**	DD – MON-YYYY

FACET INJECTION STUDY	Facet Injection Study Case Report Form (CRF)	
	Participant Initials:	Site ID: Participant Trial ID:

VISIT B - BEST USUAL CARE TREATMENT SESSION 1

1. Date of Treatment Session: d d m o n y y y y

Please tick the modality/technique used in each session. Where subcategories are indicated, please tick all that are performed for each session. Please refer to the BUC Manual for clarification concerning elements of modality/technique.

Did the participant attend: ☐ Yes ☐ No, reason..... Or ☐ Unknown

Modality/technique	Tick (✓) YES if used, tick (✓) NO if not used for each leading category & sub-category		Provided as homework?
ACCEPTANCE (compulsory)	☐ YES	☐ NO	☐ YES
GOAL SETTING (compulsory)	☐ YES	☐ NO	☐ YES
PACING (compulsory)	☐ YES	☐ NO	☐ YES
EXERCISES (compulsory)	☐ YES	☐ NO	☐ YES
- Specific	☐ YES	☐ NO	☐ YES
- Motor control retraining/core stability	☐ YES	☐ NO	☐ YES
- Cardiovascular	☐ YES	☐ NO	☐ YES
- Strength	☐ YES	☐ NO	☐ YES
- Stretches	☐ YES	☐ NO	☐ YES
- Other exercise, please specify:_____			
ADVICE	☐ YES	☐ NO	☐ YES
- Pain terminology, mechanisms and pathways	☐ YES	☐ NO	☐ YES
- Activities of Daily Living	☐ YES	☐ NO	☐ YES
- Work and ergonomics	☐ YES	☐ NO	☐ YES
- Lifestyle changes	☐ YES	☐ NO	☐ YES
- Management of flare ups & changing symptoms	☐ YES	☐ NO	☐ YES
- Paced home exercises	☐ YES	☐ NO	☐ YES
- Other advice, please specify:_____			
MANUAL THERAPY	☐ YES	☐ NO	☐ YES
- Kaltenborn	☐ YES	☐ NO	☐ YES
- McKenzie	☐ YES	☐ NO	☐ YES
- Maitland	☐ YES	☐ NO	☐ YES
- Cyriax	☐ YES	☐ NO	☐ YES
- Osteopathic techniques	☐ YES	☐ NO	☐ YES
- Mulligans	☐ YES	☐ NO	☐ YES
- (NAGS/SNAGS/MWM)	☐ YES	☐ NO	☐ YES
- Other manual therapy, please specify:_____			
SOFT TISSUE	☐ YES	☐ NO	☐ YES
- Myo-fascial	☐ YES	☐ NO	☐ YES
- Trigger point	☐ YES	☐ NO	☐ YES
- Soft tissue massage	☐ YES	☐ NO	☐ YES
- Manipulation	☐ YES	☐ NO	☐ YES
- Soft tissue release	☐ YES	☐ NO	☐ YES
- Other soft tissue, please specify:_____			
CHALLENGING NEGATIVE THOUGHTS	☐ YES	☐ NO	☐ YES
MINDFULNESS	☐ YES	☐ NO	☐ YES

Physiotherapist/investigator undertaking Best Usual Care Treatment session :			
Name :			
Signature :		**Date signed:**	DD – MON-YYYY

VISIT B - BEST USUAL CARE TREATMENT SESSION 1

1. **Has the participant changed any medication regimes compared with those reported at diagnostic assessment visit (Visit A):**

☐ Yes—please complete the table below ☐ No—move to question 2

Drug name (trade or generic)	Dose	Unit	Frequency	Indication	Start Date (dd-mmm-yyyy) Or tick unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown

2. **Please indicate in the table below if the participant has undergone any other (non-trial specified) registered health care professional delivered treatment since the diagnostic assessment visit.**

Treatment type	Tick one: *Yes*	*No*	If Yes , record the number of visits below, or tick unknown
Physiotherapy			Number of visits: ☐ Unknown
Osteopathy			Number of visits ☐ Unknown
Chiropractic			Number of visits: ☐ Unknown
Acupuncture			Number of visits: ☐ Unknown
Other, specify.....			Number of visits: ☐ Unknown
Other, specify.....			Number of visits: ☐ Unknown

Action Needed (tick all that apply)

- ☐ None, patient deemed treatment concluded, notify WCTU
- ☐ None, patient to continue
- ☐ Discuss treatment options with colleagues
- ☐ Review management to date
- ☐ Post Query on the FIS Discussion Forum

Physiotherapist/investigator undertaking Best Usual Care Treatment session :			
Name :			
Signature :		**Date signed:**	DD – MON-YYYY

FACET INJECTION STUDY	**Facet Injection Study** Case Report Form (CRF)	
	Participant Initials:	**Site ID:** **Participant Trial ID:**

VISIT B - BEST USUAL CARE TREATMENT SESSION 2

1. Date of Treatment Session: d d m o n y y y y

Please tick the modality/technique used in each session. Where subcategories are indicated, please tick all that are performed for each session. Please refer to the BUC Manual for clarification concerning elements of modality/technique .

Did the participant attend: ☐ **Yes** ☐ **No, reason**..... **Or** ☐ **Unknown**

Modality/technique	**Tick (✓) YES if used, tick (✓) NO if not used for each leading category & sub-category**		**Provided as homework?**
ACCEPTANCE (compulsory)	☐ **YES**	☐ **NO**	☐ YES
GOAL SETTING (compulsory)	☐ **YES**	☐ **NO**	☐ YES
PACING (compulsory)	☐ **YES**	☐ **NO**	☐ YES
EXERCISES (compulsory)	☐ **YES**	☐ **NO**	☐ YES
- Specific	☐ **YES**	☐ **NO**	☐ YES
- Motor control retraining/core stability	☐ **YES**	☐ **NO**	☐ YES
- Cardiovascular	☐ **YES**	☐ **NO**	☐ YES
- Strength	☐ **YES**	☐ **NO**	☐ YES
- Stretches	☐ **YES**	☐ **NO**	☐ YES
- Other exercise, please specify:_____			
ADVICE	☐ **YES**	☐ **NO**	☐ YES
- Pain terminology, mechanisms and pathways	☐ **YES**	☐ **NO**	☐ YES
- Activities of Daily Living	☐ **YES**	☐ **NO**	☐ YES
- Work and ergonomics	☐ **YES**	☐ **NO**	☐ YES
- Lifestyle changes	☐ **YES**	☐ **NO**	☐ YES
- Management of flare ups & changing symptoms	☐ **YES**	☐ **NO**	☐ YES
- Paced home exercises	☐ **YES**	☐ **NO**	☐ YES
- Other advice, please specify:_____			
MANUAL THERAPY	☐ **YES**	☐ **NO**	☐ YES
- Kaltenborn	☐ **YES**	☐ **NO**	☐ YES
- McKenzie	☐ **YES**	☐ **NO**	☐ YES
- Maitland	☐ **YES**	☐ **NO**	☐ YES
- Cyriax	☐ **YES**	☐ **NO**	☐ YES
- Osteopathic techniques	☐ **YES**	☐ **NO**	☐ YES
- Mulligans	☐ **YES**	☐ **NO**	☐ YES
- (NAGS/SNAGS/MWM)	☐ **YES**	☐ **NO**	☐ YES
- Other manual therapy, please specify:_____			
SOFT TISSUE	☐ **YES**	☐ **NO**	☐ YES
- Myo-fascial	☐ **YES**	☐ **NO**	☐ YES
- Trigger point	☐ **YES**	☐ **NO**	☐ YES
- Soft tissue massage	☐ **YES**	☐ **NO**	☐ YES
- Manipulation	☐ **YES**	☐ **NO**	☐ YES
- Soft tissue release	☐ **YES**	☐ **NO**	☐ YES
- Other soft tissue, please specify:_____			
CHALLENGING NEGATIVE THOUGHTS	☐ **YES**	☐ **NO**	☐ YES
MINDFULNESS	☐ **YES**	☐ **NO**	☐ YES

Physiotherapist/investigator undertaking Best Usual Care Treatment session :			
Name :			
Signature :		**Date signed:**	DD – MON-YYYY

VISIT B - BEST USUAL CARE TREATMENT SESSION 2

1. **Has the participant changed any medication regimes compared with those reported at the previous treatment session visit ?**

☐ Yes—please complete the table below ☐ No—move to question 2

Drug name (trade or generic)	Dose	Unit	Frequency	Indication	Start Date (dd-mmm-yyyy) Or tick unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown

2. **Please indicate in the table below if the participant has undergone any other (non-trial specified) registered health care professional delivered treatment since the previous treatment session**

Treatment type	Tick one: *Yes*	*No*	If Yes , record the number of visits below, or tick unknown
Physiotherapy			Number of visits: ☐ Unknown
Osteopathy			Number of visits ☐ Unknown
Chiropractic			Number of visits: ☐ Unknown
Acupuncture			Number of visits: ☐ Unknown
Other, specify.....			Number of visits: ☐ Unknown
Other, specify.....			Number of visits: ☐ Unknown

Best Usual Care Session Review	Action Needed (tick all that apply)
☐ Unknown, participant did not attend	☐ None, patient deemed treatment concluded , notify WCTU
☐ Better	☐ None, patient to continue
☐ Worse	☐ Discuss treatment options with colleagues
☐ The Same	☐ Review management to date
	☐ Post Query on the FIS Discussion Forum

Physiotherapist/investigator undertaking Best Usual Care Treatment session :			
Name :			
Signature :		**Date signed:**	DD – MON-YYYY

FACET INJECTION STUDY	Facet Injection Study Case Report Form (CRF)	
	Participant Initials: Site ID:	Participant Trial ID:

VISIT B - BEST USUAL CARE TREATMENT SESSION 3

1. Date of Treatment Session: d d m o n y y y y

Please tick the modality/technique used in each session. Where subcategories are indicated, please tick all that are performed for each session. Please refer to the BUC Manual for clarification concerning elements of modality/technique .

Did the participant attend: ☐ **Yes** ☐ **No, reason.....** **Or** ☐ **Unknown**

Modality/technique	Tick (✓) YES if used, tick (✓) NO if not used for each leading category & sub-category		Provided as homework?
ACCEPTANCE	☐ **YES**	☐ **NO**	☐ YES
GOAL SETTING	☐ **YES**	☐ **NO**	☐ YES
PACING	☐ **YES**	☐ **NO**	☐ YES
EXERCISES	☐ **YES**	☐ **NO**	☐ YES
- Specific	☐ **YES**	☐ **NO**	☐ YES
- Motor control retraining/core stability	☐ **YES**	☐ **NO**	☐ YES
- Cardiovascular	☐ **YES**	☐ **NO**	☐ YES
- Strength	☐ **YES**	☐ **NO**	☐ YES
- Stretches	☐ **YES**	☐ **NO**	☐ YES
- Other exercise, please specify:_____			
ADVICE	☐ **YES**	☐ **NO**	☐ YES
- Pain terminology, mechanisms and pathways	☐ **YES**	☐ **NO**	☐ YES
- Activities of Daily Living	☐ **YES**	☐ **NO**	☐ YES
- Work and ergonomics	☐ **YES**	☐ **NO**	☐ YES
- Lifestyle changes	☐ **YES**	☐ **NO**	☐ YES
- Management of flare ups & changing symptoms	☐ **YES**	☐ **NO**	☐ YES
- Paced home exercises	☐ **YES**	☐ **NO**	☐ YES
- Other advice, please specify:_____			
MANUAL THERAPY	☐ **YES**	☐ **NO**	☐ YES
- Kaltenborn	☐ **YES**	☐ **NO**	☐ YES
- McKenzie	☐ **YES**	☐ **NO**	☐ YES
- Maitland	☐ **YES**	☐ **NO**	☐ YES
- Cyriax	☐ **YES**	☐ **NO**	☐ YES
- Osteopathic techniques	☐ **YES**	☐ **NO**	☐ YES
- Mulligans	☐ **YES**	☐ **NO**	☐ YES
- (NAGS/SNAGS/MWM)	☐ **YES**	☐ **NO**	☐ YES
- Other manual therapy, please specify:_____			
SOFT TISSUE	☐ **YES**	☐ **NO**	☐ YES
- Myo-fascial	☐ **YES**	☐ **NO**	☐ YES
- Trigger point	☐ **YES**	☐ **NO**	☐ YES
- Soft tissue massage	☐ **YES**	☐ **NO**	☐ YES
- Manipulation	☐ **YES**	☐ **NO**	☐ YES
- Soft tissue release	☐ **YES**	☐ **NO**	☐ YES
- Other soft tissue, please specify:_____			
CHALLENGING NEGATIVE THOUGHTS	☐ **YES**	☐ **NO**	☐ YES
MINDFULNESS	☐ **YES**	☐ **NO**	☐ YES

Physiotherapist/investigator undertaking Best Usual Care Treatment session :			
Name :			
Signature :		**Date signed:**	DD – MON-YYYY

VISIT B - BEST USUAL CARE TREATMENT SESSION 3

1. **Has the participant changed any medication regimes compared with those reported at the previous treatment session visit ?**

☐ Yes—please complete the table below ☐ No—move to question 2

Drug name (trade or generic)	Dose	Unit	Frequency	Indication	Start Date (dd-mmm-yyyy) Or tick unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown

2. **Please indicate in the table below if the participant has undergone any other (non-trial specified) registered health care professional delivered treatment since the previous treatment session**

Treatment type	Tick one: *Yes*	*No*	If Yes , record the number of visits below, or tick unknown
Physiotherapy			Number of visits: ☐ Unknown
Osteopathy			Number of visits ☐ Unknown
Chiropractic			Number of visits: ☐ Unknown
Acupuncture			Number of visits: ☐ Unknown
Other, specify.....			Number of visits: ☐ Unknown
Other, specify.....			Number of visits: ☐ Unknown

Best Usual Care Session Review	Action Needed (tick all that apply)
☐ Unknown, participant did not attend	☐ None, patient deemed treatment concluded, notify WCTU
☐ Better	☐ None, patient to continue
☐ Worse	☐ Discuss treatment options with colleagues
☐ The Same	☐ Review management to date
	☐ Post Query on the FIS Discussion Forum

Physiotherapist/investigator undertaking Best Usual Care Treatment session :			
Name :			
Signature :		Date signed:	DD – MON-YYYY

FACET INJECTION STUDY	**Facet Injection Study** Case Report Form (CRF)	
	Participant Initials:	**Site ID:** / **Participant Trial ID:**

VISIT B - BEST USUAL CARE TREATMENT SESSION 4

1. Date of Treatment Session: d d m o n y y y y

Please tick the modality/technique used in each session. Where subcategories are indicated, please tick all that are performed for each session. Please refer to the BUC Manual for clarification concerning elements of modality/technique .

Did the participant attend: ☐ **Yes** ☐ **No, reason**..... **Or** ☐ **Unknown**

Modality/technique	**Tick (✓) YES if used, tick (✓) NO if not used for each leading category & sub-category**		**Provided as homework?**
ACCEPTANCE	☐ **YES**	☐ **NO**	☐ YES
GOAL SETTING	☐ **YES**	☐ **NO**	☐ YES
PACING	☐ **YES**	☐ **NO**	☐ YES
EXERCISES	☐ **YES**	☐ **NO**	☐ YES
- Specific	☐ **YES**	☐ **NO**	☐ YES
- Motor control retraining/core stability	☐ **YES**	☐ **NO**	☐ YES
- Cardiovascular	☐ **YES**	☐ **NO**	☐ YES
- Strength	☐ **YES**	☐ **NO**	☐ YES
- Stretches	☐ **YES**	☐ **NO**	☐ YES
- Other exercise, please specify:_____			
ADVICE	☐ **YES**	☐ **NO**	☐ YES
- Pain terminology, mechanisms and pathways	☐ **YES**	☐ **NO**	☐ YES
- Activities of Daily Living	☐ **YES**	☐ **NO**	☐ YES
- Work and ergonomics	☐ **YES**	☐ **NO**	☐ YES
- Lifestyle changes	☐ **YES**	☐ **NO**	☐ YES
- Management of flare ups & changing symptoms	☐ **YES**	☐ **NO**	☐ YES
- Paced home exercises	☐ **YES**	☐ **NO**	☐ YES
- Other advice, please specify:_____			
MANUAL THERAPY	☐ **YES**	☐ **NO**	☐ YES
- Kaltenborn	☐ **YES**	☐ **NO**	☐ YES
- McKenzie	☐ **YES**	☐ **NO**	☐ YES
- Maitland	☐ **YES**	☐ **NO**	☐ YES
- Cyriax	☐ **YES**	☐ **NO**	☐ YES
- Osteopathic techniques	☐ **YES**	☐ **NO**	☐ YES
- Mulligans	☐ **YES**	☐ **NO**	☐ YES
- (NAGS/SNAGS/MWM)	☐ **YES**	☐ **NO**	☐ YES
- Other manual therapy, please specify:_____			
SOFT TISSUE	☐ **YES**	☐ **NO**	☐ YES
- Myo-fascial	☐ **YES**	☐ **NO**	☐ YES
- Trigger point	☐ **YES**	☐ **NO**	☐ YES
- Soft tissue massage	☐ **YES**	☐ **NO**	☐ YES
- Manipulation	☐ **YES**	☐ **NO**	☐ YES
- Soft tissue release	☐ **YES**	☐ **NO**	☐ YES
- Other soft tissue, please specify:_____			
CHALLENGING NEGATIVE THOUGHTS	☐ **YES**	☐ **NO**	☐ YES
MINDFULNESS	☐ **YES**	☐ **NO**	☐ YES

Physiotherapist/investigator undertaking Best Usual Care Treatment session :			
Name :			
Signature :		**Date signed:**	DD – MON-YYYY

FACET INJECTION STUDY	**Facet Injection Study** Case Report Form (CRF)	
	Participant Initials: ___ ___ ___ **Site ID:** ___ ___ ___ ___ ___ **Participant Trial ID:** ___ ___ ___	

VISIT B - BEST USUAL CARE TREATMENT SESSION 4

1. **Has the participant changed any medication regimes compared with those reported at the previous treatment session visit ?**

☐ Yes—please complete the table below ☐ No—move to question 2

Drug name (trade or generic)	Dose	Unit	Frequency	Indication	Start Date (dd-mmm-yyyy) Or tick unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown

2. **Please indicate in the table below if the participant has undergone any other (non-trial specified) registered health care professional delivered treatment since the previous treatment session**

Treatment type	Tick one: *Yes*	*No*	If Yes , record the number of visits below, or tick unknown
Physiotherapy			Number of visits: ☐ Unknown
Osteopathy			Number of visits ☐ Unknown
Chiropractic			Number of visits: ☐ Unknown
Acupuncture			Number of visits: ☐ Unknown
Other, specify.....			Number of visits: ☐ Unknown
Other, specify.....			Number of visits: ☐ Unknown

Best Usual Care Session Review	Action Needed (tick all that apply)
☐ Unknown, participant did not attend	☐ None, patient deemed treatment concluded
☐ Better	☐ None, patient to continue
☐ Worse	☐ Discuss treatment options with colleagues
☐ The Same	☐ Review management to date
	☐ Post Query on the FIS Discussion Forum

Physiotherapist/investigator undertaking Best Usual Care Treatment session :			
Name :			
Signature :		**Date signed:**	DD – MON-YYYY

FACET INJECTION STUDY	**Facet Injection Study** Case Report Form (CRF)	
	Participant Initials:	**Site ID:** / **Participant Trial ID:**

VISIT B - BEST USUAL CARE TREATMENT SESSION 5

1. Date of Treatment Session: d d m o n y y y y

Please tick the modality/technique used in each session. Where subcategories are indicated, please tick all that are performed for each session. Please refer to the BUC Manual for clarification concerning elements of modality/technique .

Did the participant attend: ☐ **Yes** ☐ **No, reason**..... **Or** ☐ **Unknown**

Modality/technique	Tick (✓) YES if used, tick (✓) NO if not used for each leading category & sub-category		Provided as homework?
ACCEPTANCE	☐ **YES**	☐ **NO**	☐ YES
GOAL SETTING	☐ **YES**	☐ **NO**	☐ YES
PACING	☐ **YES**	☐ **NO**	☐ YES
EXERCISES	☐ **YES**	☐ **NO**	☐ YES
- Specific	☐ **YES**	☐ **NO**	☐ YES
- Motor control retraining/core stability	☐ **YES**	☐ **NO**	☐ YES
- Cardiovascular	☐ **YES**	☐ **NO**	☐ YES
- Strength	☐ **YES**	☐ **NO**	☐ YES
- Stretches	☐ **YES**	☐ **NO**	☐ YES
- Other exercise, please specify:_____			
ADVICE	☐ **YES**	☐ **NO**	☐ YES
- Pain terminology, mechanisms and pathways	☐ **YES**	☐ **NO**	☐ YES
- Activities of Daily Living	☐ **YES**	☐ **NO**	☐ YES
- Work and ergonomics	☐ **YES**	☐ **NO**	☐ YES
- Lifestyle changes	☐ **YES**	☐ **NO**	☐ YES
- Management of flare ups & changing symptoms	☐ **YES**	☐ **NO**	☐ YES
- Paced home exercises	☐ **YES**	☐ **NO**	☐ YES
- Other advice, please specify:_____			
MANUAL THERAPY	☐ **YES**	☐ **NO**	☐ YES
- Kaltenborn	☐ **YES**	☐ **NO**	☐ YES
- McKenzie	☐ **YES**	☐ **NO**	☐ YES
- Maitland	☐ **YES**	☐ **NO**	☐ YES
- Cyriax	☐ **YES**	☐ **NO**	☐ YES
- Osteopathic techniques	☐ **YES**	☐ **NO**	☐ YES
- Mulligans	☐ **YES**	☐ **NO**	☐ YES
- (NAGS/SNAGS/MWM)	☐ **YES**	☐ **NO**	☐ YES
- Other manual therapy, please specify:_____			
SOFT TISSUE	☐ **YES**	☐ **NO**	☐ YES
- Myo-fascial	☐ **YES**	☐ **NO**	☐ YES
- Trigger point	☐ **YES**	☐ **NO**	☐ YES
- Soft tissue massage	☐ **YES**	☐ **NO**	☐ YES
- Manipulation	☐ **YES**	☐ **NO**	☐ YES
- Soft tissue release	☐ **YES**	☐ **NO**	☐ YES
- Other soft tissue, please specify:_____			
CHALLENGING NEGATIVE THOUGHTS	☐ **YES**	☐ **NO**	☐ YES
MINDFULNESS	☐ **YES**	☐ **NO**	☐ YES

Physiotherapist/investigator undertaking Best Usual Care Treatment session :			
Name :			
Signature :		**Date signed:**	DD – MON-YYYY

VISIT B - BEST USUAL CARE TREATMENT SESSION 5

1. **Has the participant changed any medication regimes compared with those reported at the previous treatment session visit ?**

☐ Yes—please complete the table below ☐ No—move to question 2

Drug name (trade or generic)	Dose	Unit	Frequency	Indication	Start Date (dd-mmm-yyyy) Or tick unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown

2. **Please indicate in the table below if the participant has undergone any other (non-trial specified) registered health care professional delivered treatment since the previous treatment session**

Treatment type	Tick one: *Yes*	*No*	If Yes , record the number of visits below, or tick unknown
Physiotherapy			Number of visits: ___ ☐ Unknown
Osteopathy			Number of visits ___ ☐ Unknown
Chiropractic			Number of visits: ___ ☐ Unknown
Acupuncture			Number of visits: ___ ☐ Unknown
Other, specify.....			Number of visits: ___ ☐ Unknown
Other, specify.....			Number of visits: ___ ☐ Unknown

Best Usual Care Session Review	Action Needed (tick all that apply)
☐ Unknown, participant did not attend	☐ None, patient deemed treatment concluded, notify WCTU
☐ Better	☐ None, patient to continue
☐ Worse	☐ Discuss treatment options with colleagues
☐ The Same	☐ Review management to date
	☐ Post Query on the FIS Discussion Forum

Physiotherapist/investigator undertaking Best Usual Care Treatment session :			
Name :			
Signature :		**Date signed:**	DD – MON-YYYY

FACET INJECTION STUDY	Facet Injection Study Case Report Form (CRF)	
	Participant Initials:	Site ID: Participant Trial ID:

VISIT B - BEST USUAL CARE TREATMENT SESSION 6

1. Date of Treatment Session: d d m o n y y y y

Please tick the modality/technique used in each session. Where subcategories are indicated, please tick all that are performed for each session. Please refer to the BUC Manual for clarification concerning elements of modality/technique .

Did the participant attend: ☐ **Yes** ☐ **No, reason**..... **Or** ☐ **Unknown**

Modality/technique	Tick (✓) YES if used, tick (✓) NO if not used for each leading category & sub-category		Provided as homework?
ACCEPTANCE	☐ **YES**	☐ **NO**	☐ YES
GOAL SETTING	☐ **YES**	☐ **NO**	☐ YES
PACING	☐ **YES**	☐ **NO**	☐ YES
EXERCISES	☐ **YES**	☐ **NO**	☐ YES
- Specific	☐ **YES**	☐ **NO**	☐ YES
- Motor control retraining/core stability	☐ **YES**	☐ **NO**	☐ YES
- Cardiovascular	☐ **YES**	☐ **NO**	☐ YES
- Strength	☐ **YES**	☐ **NO**	☐ YES
- Stretches	☐ **YES**	☐ **NO**	☐ YES
- Other exercise, please specify:_____			
ADVICE	☐ **YES**	☐ **NO**	☐ YES
- Pain terminology, mechanisms and pathways	☐ **YES**	☐ **NO**	☐ YES
- Activities of Daily Living	☐ **YES**	☐ **NO**	☐ YES
- Work and ergonomics	☐ **YES**	☐ **NO**	☐ YES
- Lifestyle changes	☐ **YES**	☐ **NO**	☐ YES
- Management of flare ups & changing symptoms	☐ **YES**	☐ **NO**	☐ YES
- Paced home exercises	☐ **YES**	☐ **NO**	☐ YES
- Other advice, please specify:_____			
MANUAL THERAPY	☐ **YES**	☐ **NO**	☐ YES
- Kaltenborn	☐ **YES**	☐ **NO**	☐ YES
- McKenzie	☐ **YES**	☐ **NO**	☐ YES
- Maitland	☐ **YES**	☐ **NO**	☐ YES
- Cyriax	☐ **YES**	☐ **NO**	☐ YES
- Osteopathic techniques	☐ **YES**	☐ **NO**	☐ YES
- Mulligans	☐ **YES**	☐ **NO**	☐ YES
- (NAGS/SNAGS/MWM)	☐ **YES**	☐ **NO**	☐ YES
- Other manual therapy, please specify:_____			
SOFT TISSUE	☐ **YES**	☐ **NO**	☐ YES
- Myo-fascial	☐ **YES**	☐ **NO**	☐ YES
- Trigger point	☐ **YES**	☐ **NO**	☐ YES
- Soft tissue massage	☐ **YES**	☐ **NO**	☐ YES
- Manipulation	☐ **YES**	☐ **NO**	☐ YES
- Soft tissue release	☐ **YES**	☐ **NO**	☐ YES
- Other soft tissue, please specify:_____			
CHALLENGING NEGATIVE THOUGHTS	☐ **YES**	☐ **NO**	☐ YES
MINDFULNESS	☐ **YES**	☐ **NO**	☐ YES

Physiotherapist/investigator undertaking Best Usual Care Treatment session :			
Name :			
Signature :		**Date signed:**	DD – MON-YYYY

FACET INJECTION STUDY	**Facet Injection Study** Case Report Form (CRF)	
	Participant Initials: ____ ____ ____ **Site ID:** ____ ____ ____	**Participant Trial ID:** ____ ____ ____ ____

VISIT B - BEST USUAL CARE TREATMENT SESSION 6

1. **Has the participant changed any medication regimes compared with those reported at the previous treatment session visit ?**

☐ Yes—please complete the table below ☐ No—move to question 2

Drug name (trade or generic)	Dose	Unit	Frequency	Indication	Start Date (dd-mmm-yyyy) Or tick unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown
					___/___/___ ☐ Unknown

2. **Please indicate in the table below if the participant has undergone any other (non-trial specified) registered health care professional delivered treatment since the previous treatment session**

Treatment type	Tick one: *Yes*	*No*	If Yes , record the number of visits below, or tick unknown
Physiotherapy			Number of visits: ___ ☐ Unknown
Osteopathy			Number of visits ___ ☐ Unknown
Chiropractic			Number of visits: ___ ☐ Unknown
Acupuncture			Number of visits: ___ ☐ Unknown
Other, specify.....			Number of visits: ___ ☐ Unknown
Other, specify.....			Number of visits: ___ ☐ Unknown

Best Usual Care Session Review	Action Needed (tick all that apply)
☐ Unknown, participant did not attend	☐ None, patient deemed treatment concluded, notify WCTU
☐ Better	☐ None, patient to continue
☐ Worse	☐ Discuss treatment options with colleagues
☐ The Same	☐ Review management to date
	☐ Post Query on the FIS Discussion Forum

Physiotherapist/investigator undertaking Best Usual Care Treatment session :			
Name :			
Signature :		**Date signed:**	DD – MON-YYYY

VISIT C - INJECTION

☐ **Not applicable, participant randomised to Best Usual Care only**

1. Date of injection: d d m o n y y y y

2. Is the participant still considered suitable for the study facet joint injection procedure ?

☐ Yes - ensure standard NHS/Trust consent signed by participant for injection procedure

☐ No*, specify the reason(s) why ……

……

……

……

***If No, is the participant still willing to continue with the BUC treatment sessions ?**

☐ Yes - continue schedule BUC treatment sessions

☐ No - complete withdrawal CRF page and end of study treatment CRF page

3. Was the injection postponed or rescheduled by the investigator or other trial personnel?

☐ Yes * ☐ No

* If yes, please specify the reason why below:

☐ Equipment Failure

☐ Participant underlying local infection

☐ Other, please specify reason ; ……

……

Investigator responsible for injection			
Name :			
Signature :		**Date signed:**	DD – MON-YYYY

FACET INJECTION STUDY	**Facet Injection Study** Case Report Form (CRF)	
	Participant Initials: **Site ID:**	**Participant Trial ID:**

VISIT C - INJECTION

1. Pain outcomes reported by participant immediately before injection (within 60 minutes):

On a 0 to 10 scale (0 = no pain, 10 = worst pain) what is the participant's average pain reported immediately pre injection? *(circle only one of the reported number)*

0 1 2 3 4 5 6 7 8 9 10

2. Start time of injection: ☐☐ : ☐☐ *24 hour format*

3. End time of injection: ☐☐ : ☐☐ *24 hour format*

4.

Confirmation of injectate preparation:	**Dose**	**Batch no.:**	**Expiry date:**
Levobupivacaine 5mg/ml	☐.☐ ml	.....	d d m o n y y y y
Triamcinolone 10mg/ml	☐.☐ ml		d d m o n y y y y

5. Total No. of facet joints injected: ☐ (number 1 to 6 inclusive)

Joints Injected	**LEFT side injected and volume administered**	**RIGHT side injected and volume administered**
L3/L4 ☐ Yes ☐ No	☐ Yes, Volume: ☐.☐ ml ☐ No	☐ Yes, Volume: ☐.☐ ml ☐ No
L4/L5 ☐ Yes ☐ No	☐ Yes, Volume: ☐.☐ ml ☐ No	☐ Yes, Volume: ☐.☐ ml ☐ No
L5/S1 ☐ Yes ☐ No	☐ Yes, Volume: ☐.☐ ml ☐ No	☐ Yes, Volume: ☐.☐ ml ☐ No

Investigator responsible for injection:			
Name :			
Signature :		**Date signed:**	DD – MON-YYYY

FACET INJECTION STUDY	**Facet Injection Study** Case Report Form (CRF)	
	Participant Initials:	**Site ID:** **Participant Trial ID:**

VISIT C - INJECTION

1. **Resistance to injection:** Yes* ☐ No ☐

   *** If Yes, please tick the reasons for resistance:**

   ☐ Abutment of the needle bevel to a surface

   ☐ Filing of the intra-articular space

   ☐ Other, Specify reason;.....

2. **Pain outcomes reported by participant immediately after injection (within 60 minutes)**
   On a 0 to 10 scale (0 = no pain, 10 = worst pain) what is the participant's average pain reported pain immediately after injection? (*circle only one of the reported number*)

0	1	2	3	4	5	6	7	8	9	10

3. **Was the injection procedure performed in accordance with the study protocol and injection manual?**

   ☐ Yes

   ☐ No Specify reason why;.....

   .....

4. **Cumulative exposure time:** ☐☐ : ☐☐ *24 hour format*

5. **Total radiation exposure from facet joint injection procedure:** ☐ . ☐ mSv

Investigator responsible for injection:			
Name :			
Signature :		**Date signed:**	DD – MON-YYYY

VISIT C - INJECTION

Injection site monitoring – immediately Pre injection (within 5-10 minutes before injection)

☐ **Not Done**, specify reason why: .....

1. **Time observed:** ☐☐ : ☐☐ *24 hour format*

2. **Finding—Tick all that apply:**
   - ☐ normal
   - ☐ bleeding
   - ☐ haematoma
   - ☐ redness
   - ☐ infection
   - ☐ other, specify:.....

Injection site monitoring – Post injection (within 60 minutes post injection)

☐ **Not Done**, specify reason why: .....

3. **Time observed:** ☐☐ : ☐☐ *24 hour format*

4. **Finding—Tick all that apply:**
   - ☐ normal
   - ☐ bleeding
   - ☐ haematoma
   - ☐ redness
   - ☐ infection
   - ☐ other, specify:.....

5. **Was the participant provided with post injection advice in accordance with current hospital procedures ?**

   ☐ Yes ☐ No

Investigator responsible for injection:			
Name :			
Signature :		**Date signed:**	DD – MON-YYYY

END OF ALLOCATED TREATMENT—SUMMARY

1. **Did the participant complete the study allocated treatment?**

   ☐ **Yes** ☐ **No ***

2. **Date and time allocated treatments ended :**

   d d m o n y y y y H H M M

*** If No, specify the primary reason for participant discontinuation/withdrawal:**

……

……

……

3. **At the end of the allocated treatment, what action is suggested for the participant ?**

   ☐ Refer back to participant's GP for additional treatment(s)

   ☐ No further treatment advised

   ☐ Other, please specify : ……

   ……

Instruction to site: Please check and ensure no changes are required to participant contact details. If any details have changed, please complete a new Participant Contact Details Form to ensure postal follow up questionnaires at 3, 6 and 12m are mailed out from WCTU to participant correct address. Please ensure the study enrolment log is updated.

INVESTIGATOR STATEMENT			
I certify that I have reviewed this case report form for this participant and verify to the best of my knowledge that the information contained herein is true, accurate and complete.			
Name :			
Signature :		**Date signed:**	DD – MON-YYYY

Additional Information Form

Please use this page to provide any additional information, comments or details relating to the information or study procedures on the above referenced participant:

Page No:	Visit	Question Ref	Comments

General Comments:

Physiotherapist/investigator signature

Name :			
Signature :		**Date signed:**	DD – MON-YYYY