

Randomized Trial

Intraarticular Facet Injections for Low Back Pain: Design Considerations, Consensus Methodology to Develop the Protocol for a Randomized Controlled Trial

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Background: Since the publication of guidelines by the UK National Institute for Health and Care Excellence (NICE) and the American Pain Society guidelines for low back pain in 2009 there have been deep divisions in the pain treatment community about the use of therapeutic intraarticular facet joint injections. While evidence for the effectiveness or not of intraarticular facet joint injections remains sparse, uncertainty will remain. The Warwick feasibility study, along with a concurrent study with a different design led by another group, aims to provide a stable platform from which the effectiveness and cost effectiveness of intraarticular facet joint injections added to normal care could be evaluated in randomized controlled trials (RCTs).

Objectives: To reach consensus on key design considerations for the Warwick facet feasibility study from which the study protocol and working manuals will be developed.

Study Design: A consensus conference involving expert professionals and lay members.

Methods: Preliminary work identified 5 key design considerations for deliberation at our consensus conference. Three concerned patient assessment and treatment: diagnosis of possible facet joint pain, interarticular facet joint injection technique, and best usual care. Two concerned trial analysis: a priori sub-groups and minimally important difference and are reported elsewhere. We did systematic evidence reviews of the design considerations and summarized the evidence. Our design questions and evidence summaries were distributed to all delegates. This formed the basis for discussions on the day. Clinical experts in all aspects of facet joint injection from across the UK along with lay people were invited via relevant organizations. Nominal group technique was used in 15 facilitated initial small group discussions. Further discussion and ranking was undertaken in plenary. All small group and plenary results were recorded and checked and verified post conference. Where necessary participants were contacted via email to resolve outstanding issues.

Results: Fifty-two delegates attended the conference with lay people and all relevant professions represented. Consensus was reached on the details of how to assess patients for facet joint pain, undertake the injections, and deliver usual care. Where post conference checking of results revealed errors in calculating ranking results on the day, consensus was reached by email consultation. All but 3 delegates agreed to be associated with the outcome.

Limitations: Allocating one day for discussing a wide range of topics imposed time pressure on discussion and calculation of the numerous rankings.

Conclusions: Through the use of an evidence-based, systematic, inclusive, and transparent process we have established consensus from expert health professionals in the UK, with lay input, on the clinical assessment of suspected facet joint pain, interarticular injection for facet joint pain, and best usual care for use in a feasibility study for a proposed pragmatic clinical trial of interarticular facet joint injections. This provides a strong basis for a clinical trial that will be acceptable to the pain treatment community.

Key words: Low back pain, interarticular facet joint injections, best usual care, consensus, nominal group technique

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Low back pain is number one in the global burden of disease for years lived with disability (1). The most recent UK cost of illness study is from 1998. At that time the direct health care costs of low back pain were £1,067M for the UK NHS and £565M in private health care; £28/head of population (2). A 1998 US study estimated direct health care costs as \$90,601M; \$335 per head of population (3). Much has changed since then. In the United States there has been a 2.4 fold increase in spinal fusions and a massive increase in facet joint interventions; both of which are still increasing (4,5). In response to this problem the UK National Institute of Health and Clinical Excellence (NICE) commissioned guidelines for the management of non-specific low back pain lasting between 6 weeks and one year (6). Published in 2009 they, controversially, recommended not to use a range of treatment approaches that have not been proven to be effective through randomized controlled trials (RCTs) (6,7). The excluded treatment approaches included the injection of therapeutic substances into the back. This recommendation is reported to have had the consequence of reducing the funding for pain clinic services across the UK with the consequence of reducing access to invasive procedures for both people to whom the guideline applies and those for whom it does not; that is, people with radicular pain and those with pain for more than one year. Deep divisions in the scientific and clinical communities have become clear since publication of NICE and American Pain Society guidelines for low back pain (8) which also indicated there was insufficient evidence to support the injection of therapeutic substances into the back (9). Although the methodological approach used by the American Pain Society has been challenged, The American Society of Interventional Pain Physicians also concluded that the evidence for therapeutic interaarticular facet joint injections was limited (10,11). There are a variety of different interpretations of the available evidence from RCTs and observational studies on the effectiveness of interaarticular facet joint injections (12-17). Nevertheless, there remains controversy surrounding this issue in the US and UK. In the UK the NICE guidelines are currently undergoing a review and there has been a considerable amount of new research evaluating lumbar facet joint interventions (10,18,19). However, the outcome of all this work is that these data do not constitute a robust evidence base to inform decisions about the use of therapeutic interaarticular facet joint injections. Thus there is a clear need for a trial to test

the effectiveness of adding interaarticular facet joint injections to usual care for the treatment of persistent low back pain where usual care is as recommended by NICE or the American Pain Society. It is important that the proposed trial provides data that all parties can agree on. If the trial has positive results then re-investment in this treatment will be justified. If the trial is negative its conclusions need to be sufficiently robust that all parties to the debate on current guidance are satisfied that the evidence does not support the use of therapeutic interaarticular facet joint injections. The UK National Institute for Health Research, via a specific call, is currently funding 2 feasibility studies in preparation for trials of therapeutic interaarticular facet joint injections; we are funded to do one of these studies. Our proposed study will test the addition of a therapeutic interaarticular facet joint injection to best usual care (20). A different team is funded to test the feasibility of a more explanatory trial comparing active interaarticular injection with a sham control in people with a positive diagnostic medial branch nerve block (21). These 2 studies will produce complementary data that will inform decisions on the merit of offering therapeutic interaarticular facet joint injections to selected people with low back pain. The comparative merits of these 2 trial designs, or other alternative trial designs, is beyond the scope of this paper. We will publish our overall feasibility study protocol as a separate paper.

This paper reports the design stage of our feasibility study for the proposed RCT, the Facet Injection Study (FIS) to be conducted in the UK NHS (20). The hypothesis to be tested in the proposed trial is:

For people with suspected facet joint pain contributing to persistent low back pain, adding the option of therapeutic interaarticular facet joint injections, with local anaesthetic and corticosteroids, to best usual non-invasive care available from the NHS is clinically and cost-effective.

There are methodological challenges to setting up and running such a pragmatic trial. There is considerable diagnostic uncertainty about how to identify people with pain of facet joint origin among the wider chronic low back pain population. There are a variety of injection techniques in use within the NHS. While many authors have reported their individual techniques for the therapeutic injection of lumbar facet joints there is little consensus and no guidelines or recommendations for current best practice. In the UK, it is common for a subgroup of patients with low back pain, those with

suspected facet joint pain, to be treated with an injection of local anaesthetic and steroid. The boundaries of diagnostic and therapeutic intent are blurred. Some, but not all, patients receiving interaarticular facet joint injections will be offered a functional restoration program.

Within the UK NHS it is usual practice to inject local anaesthetic and corticosteroids at the same time to avoid the need for the patient to return for a second injection; pragmatically it is this approach that needs testing. There is little agreement on the optimal conservative management/rehabilitation for patients with facet joint pain that is consistent with the NICE guidelines and can be delivered by the NHS. The measurement of outcome in low back pain trials is problematic (22-24). Although there are well established standard packages of outcome measures, the theoretical underpinning of these is poor (22,25). A recent report from the National Institutes of Health (NIH) taskforce on research standards for chronic low back pain recommends the use of 2 questions to define chronic low back pain, classifying its impact by pain intensity, pain interference, and physical function; the use of a minimum dataset to describe research participants; and reporting "responder analyses" in addition to mean outcome scores (26).

We identified 5 design considerations 2 of which were concerned with evaluation methodology (subgroup analysis and interpreting between group differences in score) and will be reported elsewhere. This paper considers the 3 design considerations concerned with patient assessment and treatment: facet joint pain diagnosis, the process of therapeutic interaarticular facet joint injection, and the management/rehabilitation of those with facet joint pain (best usual care). This paper describes our process of evidencing these considerations, gaining consensus on the design of the study at a consensus conference, and the formulation of aspects of the FIS protocol.

METHODS

The 3 stages of the study are presented in Fig. 1: i) scoping review and identification of key design considerations, ii) evidence reviews, and iii) consensus conference.

i. Scoping Reviews and Formulation of Key Design Considerations

Our study team includes pain clinicians, physical therapists, radiologists, and lay representatives as well as research methodologists. Based on scoping reviews

of clinical practice guidelines, empirical studies and related literature, and team discussion, 3 design considerations for the proposed trial were identified and questions posed, as follows:

- ◆ Diagnosis
 - What is the best choice of clinical assessment to identify patients with facet joint pain?
- ◆ Injection technique
 - What is the agreed technique for the therapeutic interaarticular injection of facet joints?
- ◆ Best usual care
 - What is the optimal conservative management/rehabilitation for patients with low back pain where facet joints have been identified as a contributing source of symptoms?

ii. Evidence Reviews

To provide evidence on each design consideration, reviews were undertaken informed by the Cochrane and Centre for Reviews and Dissemination guidelines (27,28), as outlined below.

The databases and search terms used for each of the 3 design considerations are detailed in Table 1. Data from identified literature was extracted, collated, and tabulated, and a text summary of the evidence written. For 2 of the 3 design considerations the team provided a suggested protocol based on the evidence as a starting point for discussion at the consensus conference.

iii. The Consensus Conference:

Potential conference participants were invited through relevant professional and lay organizations (Table 2). We sought participation from experts from across the UK. By expert we mean that participants were professionals or lay people with an interest in, and experience of, back pain, its treatment, and in particular its treatment with therapeutic interaarticular facet joint injections. The invitation was to a one day conference with no attendance charge and travel expenses were reimbursed. This was held at the University of Warwick on June 27, 2014.

Approximately one week before the consensus conference, a document consisting of the design considerations and related evidence was sent to all those who registered to attend.

We used nominal group technique to gain consensus. This allows for discussion while avoiding individuals or groups dominating the consensus process, and allows participants to draw on available evidence and expertise (29). We started the conference with a brief

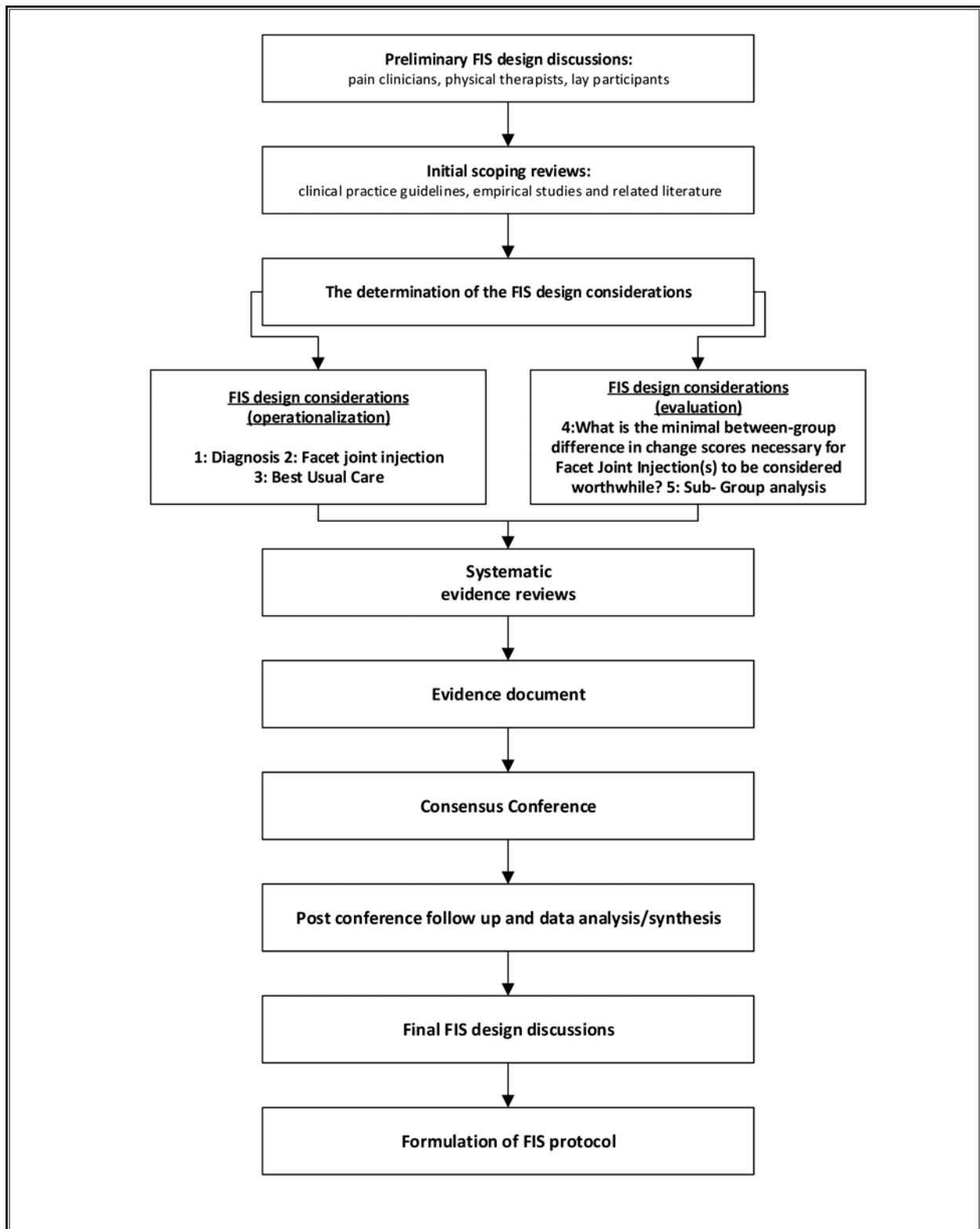


Fig. 1. Facet injection study protocol development process.

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Table 1. *Databases and search terms used in the production of evidence for each design consideration.*

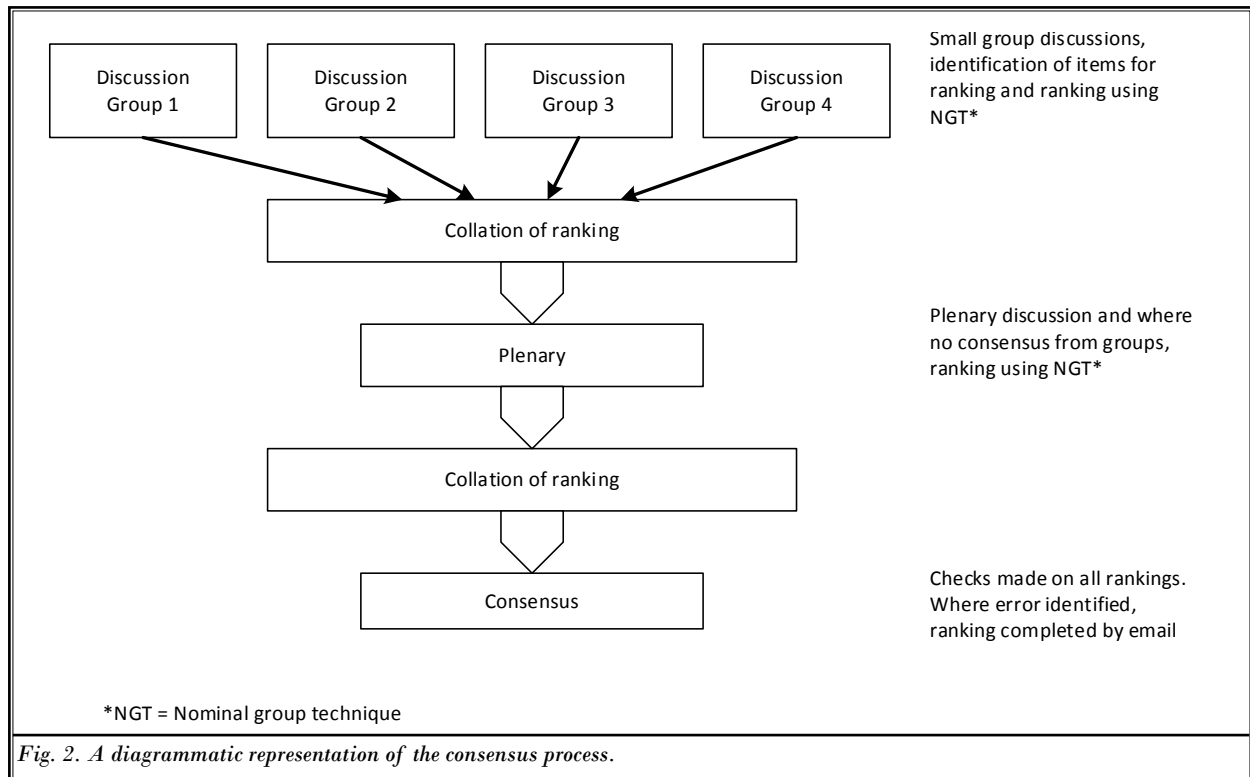
Design consideration	Diagnosis of Facet Joint Pain	The Process of therapeutic interaarticular Facet Joint Injection	Best Usual Care
Data bases	MEDLINE, EMBASE, CINAHL, Allied and Contemporary Medicine Database (AMED), BIOSIS	MEDLINE, EMBASE. Wide ranging search of key instructional texts (British Library).	MEDLINE, CINAHL and Allied and contemporary medicine database (AMED). Hand searching of seminal texts for physical therapy (as defined by NICE, 2009). Key texts in the area of physiotherapy and osteopathy were identified and searched.
Search terms	Population terms: Low back pain OR back pain OR lumbar vertebrae OR spine OR spinal diseases OR facet* OR facet joint* OR zygapophyseal joint* OR lumbar sacral pain. Intervention terms: orthopaedic OR manual OR physical OR therapeutic exercise OR exercise therapy OR rehabilitation OR physiotherapy	Target condition search terms: Low back pain OR Back pain OR Spinal pain OR Spinal diseases OR Facet Facet joint OR Zygapophysial joint OR Lumbar sacral pain OR Facet joint pain OR Spinal pain OR Facet syndrome OR Paravertebral facet pain Intervention search terms: Interaarticular facet injection(s) OR Image guided injection(s) OR Interventional spinal procedure(s) OR Fluoroscopic/ fluoroscopy OR Diagnostic OR Therapeutic Injection OR Percutaneous Spinal intervention OR Procedure Publication type search terms: Conference OR Consensus development OR Clinico-pathological Congress OR Convention OR Guideline(s) OR Recommendation(s) OR Clinical OR Best Practice(s)	Physical Therapy: Population terms: Low back pain OR back pain OR lumbar vertebrae OR spine OR spinal diseases OR facet* OR facet joint* OR zygapophyseal joint* OR lumbar sacral pain. Outcomes: Pain OR function Intervention terms: Orthopaedic OR manual OR physical OR therapeutic exercise OR exercise therapy OR rehabilitation OR physiotherapy Psychological interventions: Population terms: Low back pain OR back pain OR lumbar vertebrae OR spine OR spinal diseases OR facet* OR facet joint* OR zygapophyseal joint* OR lumbar sacral pain. Outcomes: Function Intervention terms: cognitive behavioural approach* OR cognitive behavioural principle* OR psychological approach* OR psychological principle* OR self-management OR self help

Table 2. *Organisations through which invitations to the consensus conference were distributed.*

- Professors/consultants in Pain Management via Binley mailing services (<http://www.binleys.com/>)
- British Association of Spinal Surgeons (<http://www.spinesurgeons.ac.uk/>)
- Association of British Neurologists (<http://www.theabn.org/>)
- British Society of Skeletal Radiologists (<http://www.bssr.org.uk/>)
- British Society of Interventional Radiologists (<http://www.bsir.org/>)
- Primary Care Rheumatology Society (<https://www.pcrsociety.org/>)
- Council for Allied Health Professions Research (<http://www.csp.org.uk/professional-union/research/networking-support/council-allied-health-professions-research>)
- Midlands Health Psychology Network (<http://www.mhpn.co.uk/>)
- Back Care - a lay advocacy and support organisation, (<http://www.backcare.org.uk/>)
- UNTRAP (Universities/User Teaching and Research Action Partnership) is a partnership between users of health and social care services and carers, the University of Warwick and the NHS. http://www2.warwick.ac.uk/fac/cross_fac/healthatwarwick/untrap

reminder of the key design considerations and evidence. We then held 15 small group consensus sessions each of one hour, with 5 groups meeting in parallel at any one time (Fig. 2). Small group results were fed back to a plenary where final consensus was reached. With participant consent, all sessions were audio recorded

for reference during analysis. Participants were randomly assigned to small group sessions stratified by profession (approximately 10 – 12 per group) with each participant discussing 3 different design considerations. Each small group had a trained facilitator, a scribe, and a subject expert from our team. The subject expert did not participate



in the discussions but answered questions about technical issues when invited to by the facilitator. Discussions centered on the particular design consideration, with the suggested "protocol" as a starting point where appropriate. Nominal group technique was adapted to the design consideration under discussion as described below. Each participant confidentially ranked the acceptable approaches identified by the group. Results were collated by the scribe who also took notes of the group process.

Diagnosis – assessment for facet joint pain: Participants were asked to suggest components of clinical assessment. These were then discussed to identify any that were similar and then grouped as sets forming complete clinical assessments. Participants then ranked the clinical assessments.

Injection technique: Fourteen different aspects of the process of injection had been identified. For each aspect a proposal was made for the technique to be used. Group members first identified which of these they considered acceptable. After collation of these results the facilitator invited discussion in turn on each of the aspects where there was not agreement on acceptability. For each of these, alternative processes were identified and then ranked.

Best usual care: Group participants were asked to

suggest what treatment approaches should be included in a "toolbox" from which a therapist could tailor treatment for each patient. This could include manual therapy, home exercises, and cognitive approaches. The content of the initial assessment and the number and duration of individual treatment sessions was also discussed. Group participants then identified which of these they considered acceptable. After collation of these results, the facilitator invited discussion in turn on each of the treatment approaches where there was no agreement on acceptability. The group voted on inclusion/exclusion of treatment approaches from the "toolbox" and assessment session content. They ranked alternatives for the number/duration of individual treatment sessions.

Results from all the small group sessions were collated and presented to the plenary session. Where small group results were consistent no further discussion took place. Where there were inconsistencies between small group results, these were discussed and further ranking was undertaken, collated, and reported to the plenary. We discussed and re-ranked issues until one option was clearly the preferred option and there was no objection to its adoption from conference delegates.

Post Conference

All results were checked and verified from all small group sessions and the plenary. A small number of errors were found in the collation of rankings. The team therefore contacted participants with specific expertise via email to clarify and reach a consensus on these items containing errors.

Our draft protocol for the FIS was edited to reflect the results of the consensus process.

RESULTS

Evidence Reviews

Our 3 evidence reviews informed the following design considerations: 1. Diagnosis (of facet joint pain). 2. Therapeutic intraarticular facet joint injection (technique). 3. Best usual care.

Figure 3 shows the evidence review process for each of the 3 reviews.

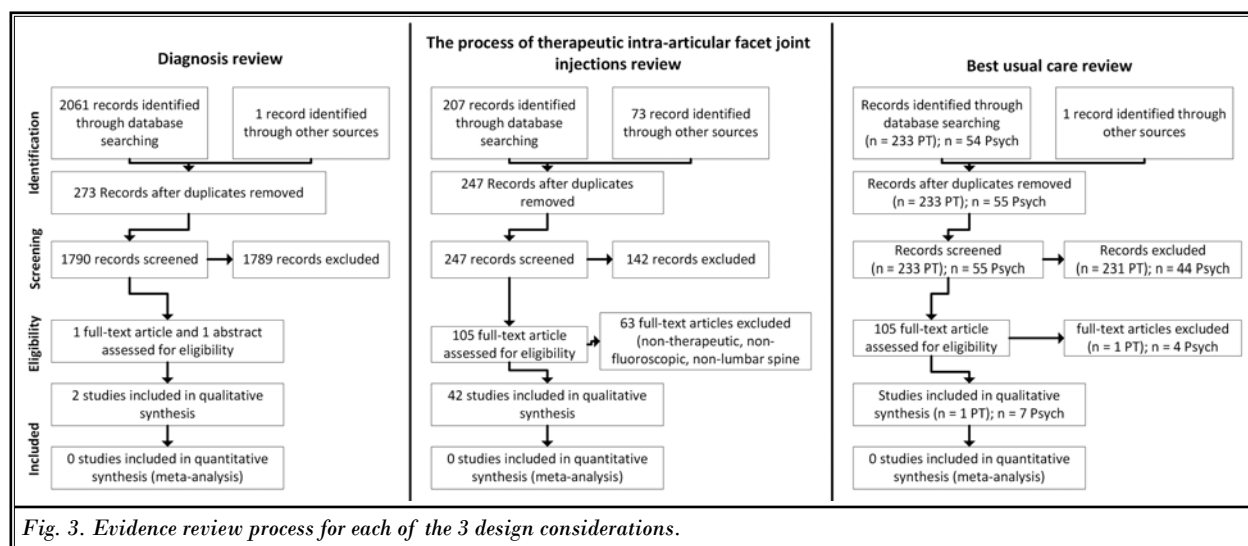


Fig. 3. Evidence review process for each of the 3 design considerations.

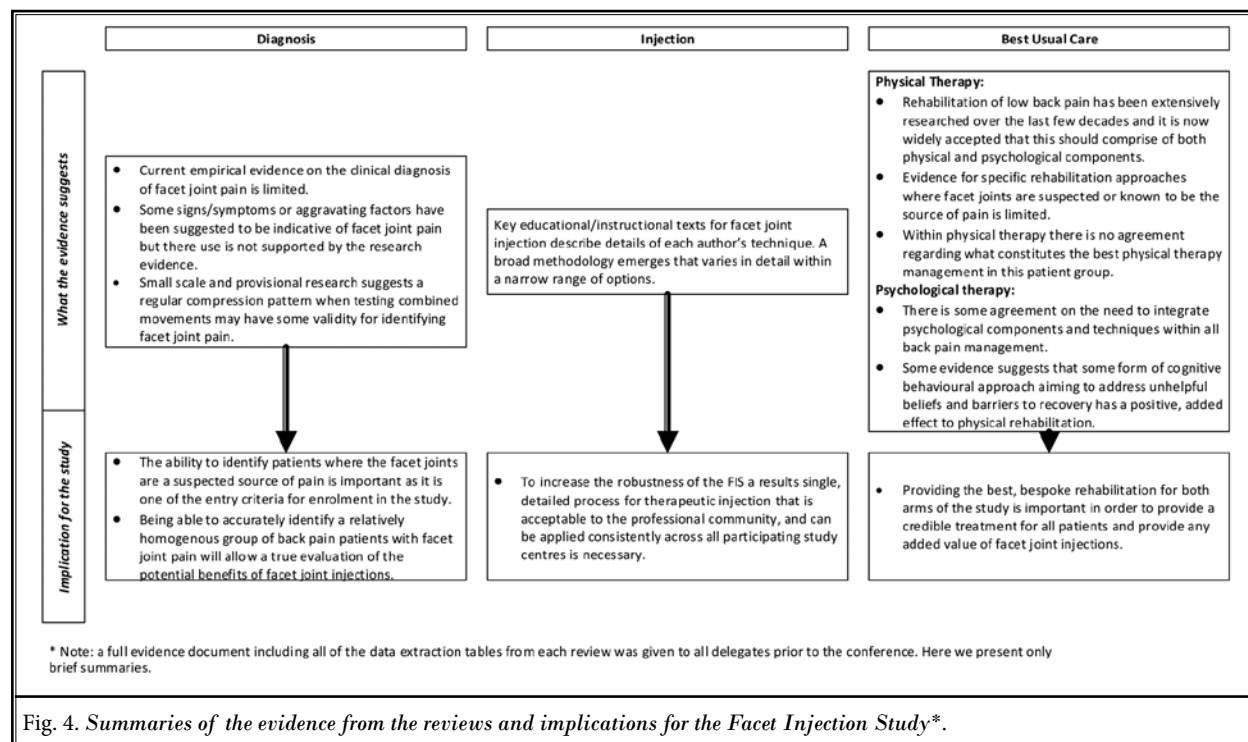


Fig. 4. Summaries of the evidence from the reviews and implications for the Facet Injection Study*.

In Fig. 4 we summarize the evidence from the reviews and its implications for the FIS.

As noted earlier a protocol based on the evidence reviews for injection technique and best usual care was presented as a starting point for discussion. These are

presented in Figs. 5 and 6.

Consensus Conference

Fifty-seven people confirmed their attendance of which 52 attended on the day. Table 2 summarizes

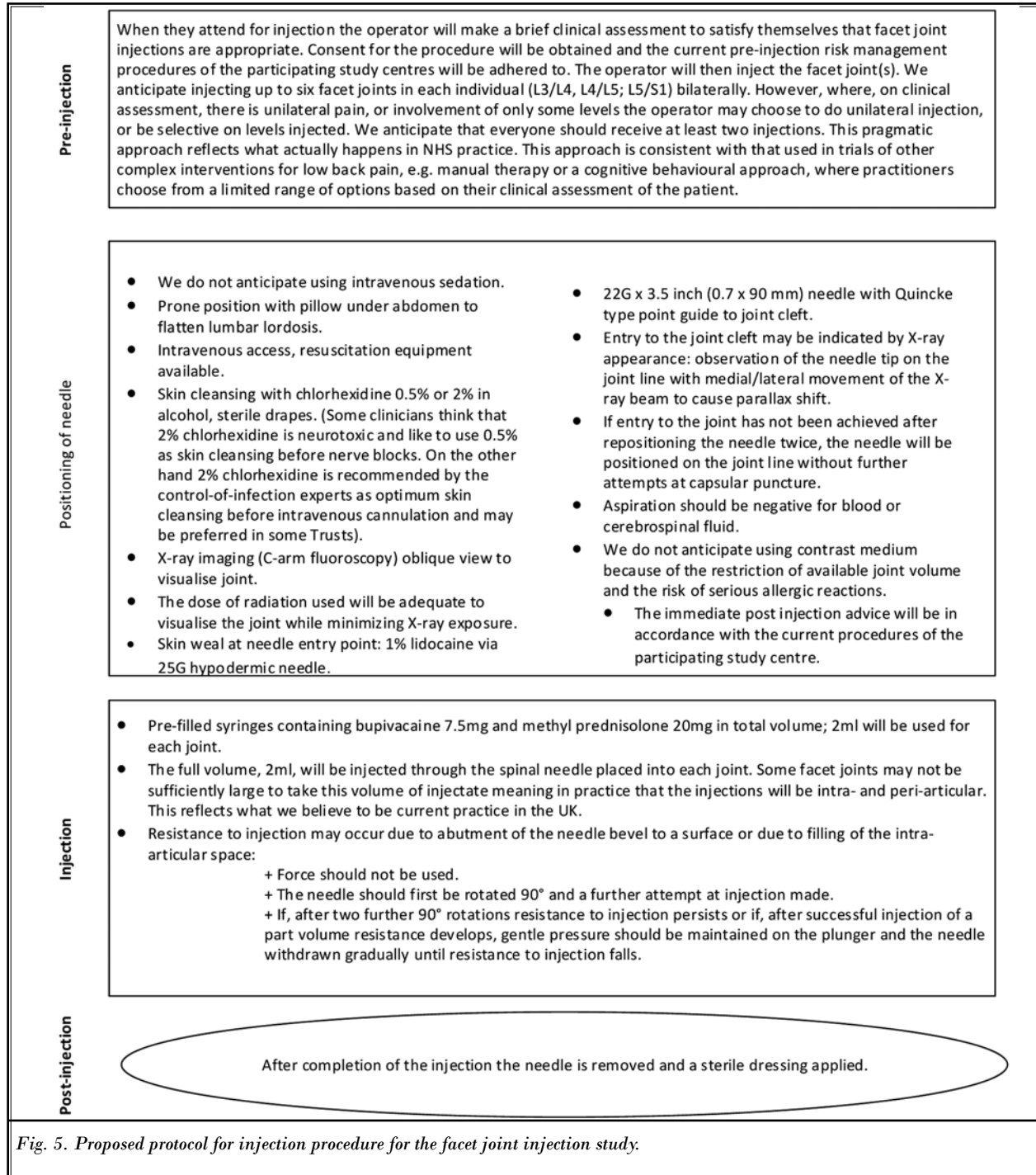
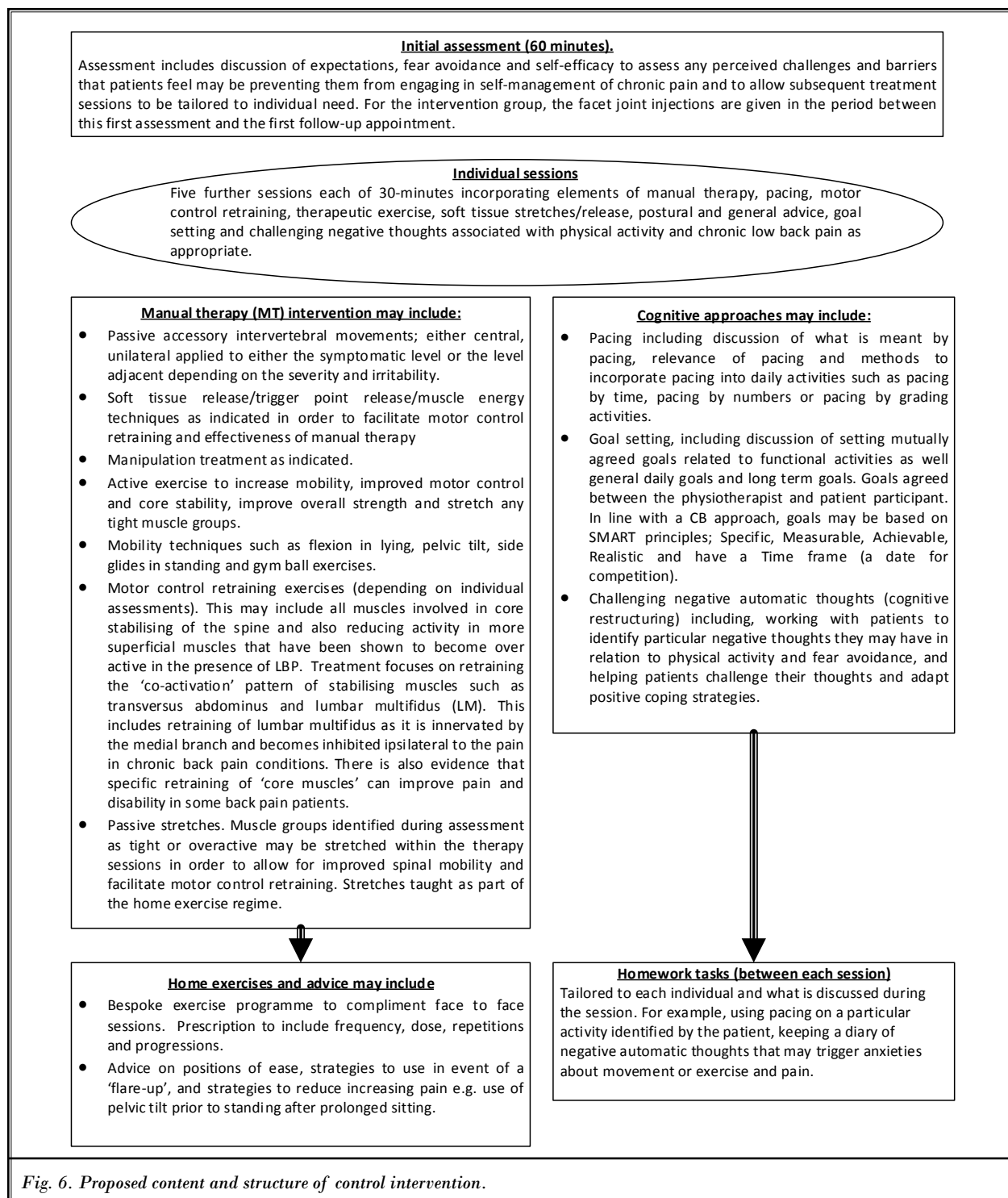


Fig. 5. Proposed protocol for injection procedure for the facet joint injection study.

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their professional or lay roles. Of the 52 attendees, 3 delegates asked not to be associated with the final consensus document. One delegate was not happy with the way the day was organized and with the involve-

ment of lay persons; one did not agree with having a physiotherapist led best usual care package; one noted no conflict but stated they felt unable to contribute as they were not statistically minded. All other attendees agreed to being identified as part of the consensus group.

We present the results from the consensus conference for each of the 3 design considerations. Tables 4, 5, and 6 present the results from the small group sessions which were taken forward to the plenary session and the plenary discussion. As these are contested issues, for transparency, we present the details of the process of reaching consensus in these tables.

Diagnosis (Table 3): The 4 diagnosis group sessions all approached the problem in different ways. In 3 of

Table 3. Number of consensus conference attendees categorized by professional/lay role.

Pain consultants and physicians	19
Anaesthetists	6
Physiotherapist or Physical specialists	12
Academics	4
Psychologists	3
Radiographers	2
Lay representatives	6

Table 4. Group and plenary results from Facet injection Study Consensus Conference looking at what is the best choice of clinical assessment to identify patients with suspected facet joint pain.

<p>Diagnosis group 1 Group generated list of 7 options:</p> <p>a) Extension and Ipsilateral side bending (standing) b) Extension and Ipsilateral rotation (prone) c) Psychological distress d) Para-Median tenderness e) MRI Lumbar spine W. Hypertrophic facet joints or fluid f) Personality inventory g) Focal low back pain</p> <p>The first round of ranking excluded: e & f</p> <p>The top 5 were then ranked again:</p> <p>Rank 1: G: Focal low back pain Rank 2: A: Extension / Ipsilateral side bending (standing) Rank 3: D: Para-Median tenderness Rank 4: C: Psychological distress Rank 5: B: Extension and Ipsilateral rotation (prone)</p>	<p>Diagnosis group 2 Group did not vote but agreed on a diagnostic pathway (outlined below).</p> <p>HISTORY (in. absence of Red Flags)</p> <ul style="list-style-type: none"> • Gradual onset (usual) • Lumbar sacral • Localised (no pain below knee) • back pain predominant feature • No neurological symptoms • Relieved at rest • Mechanical presentation • Worse on weight bearing • Worse on rotation and extension • Functional activities • Realistic expectations • Clinical reasoning of psycho-social factors • Absence of cough/sneeze/Valsalva symptoms <p>CLINICAL FINDINGS</p> <ul style="list-style-type: none"> • Active ROM extension, Ipsilateral sf, Ipsilateral rotation • Combined movements • Pain on local palpation • Absence of wide-spread hyperalgesia and analodynia • No neural tensions signs • Psycho-social screening tool • Flexion not aggravating combined movement • Pain <ul style="list-style-type: none"> Quality (aching) On rising in morning Variable Non-neurologic 	<p>Diagnosis group 3 Group agreed a list of signs and symptoms:</p> <p>Signs:</p> <ul style="list-style-type: none"> • Localised tenderness (para-spinal) • Localised tenderness over joint • No tenderness on sacroiliac joint palpation • No pain provocation on straight leg raise (to exclude neural tension) <p>Symptoms:</p> <ul style="list-style-type: none"> • Pain increases on standing for long periods • Pain increases when climbing stairs • Pain increases on extension • Pain increases on lateral rotation • Pain decreases when lying down • Pain decreases on flexion • Can have radiation to back and thigh + buttocks but not below knee • No pain radiating to groin • Absence of Radicular symptoms and signs • Time > 3 months • Had course of physiotherapy that has not resolved back pain <p>Based on the list of signs and symptoms the group generated a further list that was ranked:</p> <p>A. All signs listed plus all symptoms minus morning stiffness, time >3 months B. As A. time > 1 year C. As A. time > 6 months D. As A. time > 1 year and unsuccessful course of physiotherapy E. As A. time plus MRI F. As D. time PLUS MRI G. As A. plus diagnostic injection</p> <p>After an initial ranking a further ranking produced a top three options: Rank 1: (D), Rank 2 (A), Rank 3: (C).</p>	<p>Diagnosis group 4 Group generated list of 18 items and votes were cast on acceptability:</p> <p>A: Diagnostic injection (5 votes) B: Pain increase on extension (7 votes) C: Pain increase on twisting movement (3 votes) D: Pain increase on palpation (6 votes) E: Pain increase extension and rotation (7 votes) F: Pain increase lateral flexion – towards painful side (6 votes) G: No normal MRI/Radiological evidence4 H: Rising from flexion (7 votes) I: No red flags (inc Radicular symptoms) (7 votes) J: No Sacro Iliac joint pain (pain provocation test) (7 votes) K: Pain on standing (5 votes) L: Pain on walking (3 votes) M: Patients pain distribution para vertebral (6 votes) N: Age > 35 (4 votes) O: BMI > 40 (3 votes) P: + Decrease in pain in opposite movements (3 votes) Q: Extension and lateral flexion (7 votes) R: Pain increase walking up or down hill (4 votes)</p> <p>Four groups were generated starting with all items with the highest acceptability score (which was 7) these were then ranked.</p> <p>Rank 1: (Z) X + D + M Rank 2: (Y) X + D Rank 3: (W) X + P Rank 4: (X) B + E + H + I + J + Q</p>
<p>Plenary discussions and outcomes Results groups sessions were combined and presented for discussion The following option was discussed: Increased pain on extension Increased pain on rotation</p>	<p>Increased pain on rising from flexion Increased pain on extension/lateral flexion No radicular symptoms No SI joint pain Pain provocation test There was no final vote on this item on the day. Consensus was reached Post-conference; via email voting.</p>	<p>Participants were asked the vote on the following being 'acceptable'.</p> <ol style="list-style-type: none"> 1. Increased pain unilaterally or bilaterally, on lumbar para-spinal palpation AND 2. Increased low back pain on one or more of the following; extension (more than flexion), rotation, extension/side flexion, extension/rotation AND 	<ol style="list-style-type: none"> 3. No radicular symptoms (defined as pain radiating below the knee) AND 4. No sacro-iliac joint pain elicited using a pain provocation test. <p>Question issued to 45 physios/scope practitioners/psychologists. Responses received: 23. Acceptable; YES = 22, NO = 1</p>

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Table 5. Group and plenary Results from Facet Injection Study Consensus Conference looking at what is the agreed technique for the injection of facet joints.

<p>The 14 Injection topics open for discussion/agreement 1 Pre – injection consent/risk management 2 Processes used to select facet joints to be injected 3 Identification and visualisation of the selected joints 4 Positioning of the patient</p>	<p>5 Skin cleansing/sterilisation methods/materials 6 Administration of local anaesthetic/composition 7 Gauge/type/length of needle 8 Method to approach joint 9 Methods used to confirm intra-articular positioning of needle</p>	<p>10 Dose of radiation 11 Optimal type/configuration of X-ray machine/equipment etc. 12 Injectate volume 13 Injectate composition 14 After care advice</p>	<p>Groups voted on an item being 'acceptable' (i.e. not necessarily what they themselves would do or advise but an acceptable method/technique). Items with disagreements were discussed, alternatives suggested and voted/ on or ranked.</p>
<p>Group 1. Injection Technique There was consensus as per protocol for items: 1, 4, 5, 6, 7, 8 & 11</p> <p>Item 2 was discussed as two from the group found the protocol not acceptable. Following discussion, 3 Options ranked: Rank 1: (A) As protocol Rank 2: (B) As protocol but 8 joints not 6 as maximum Rank 3: (C) As protocol 'A' but one of the joints must be L5/S1</p> <p>Comments noted against item 2: Interval between injections 3 – 6 minutes?</p> <p>Two found items (3 & 9) not acceptable (there was no time for discussion on these)</p> <p>Item 10 was discussed as a number in the group found protocol not acceptable. Following discussion, 3 Options ranked: Rank 1(X): As protocol Rank 2(Z): Intermittent Fluoroscopy Rank 3 (Y): Upper limit of radiation that is agreed locally</p> <p>Item 11 was discussed as three in the group found protocol not acceptable. Following discussion, 4 Options ranked: Rank 1(D): As protocol but with 1ml Levo Bupivacaine Rank 2(C): As protocol using Levo Bupivacaine Rank 3(B): 1ml instead of 2ml (same drugs) Rank 4 (A): As protocol</p> <p>Comments noted against item 11:</p> <ul style="list-style-type: none"> Levo Bupivacaine (less cardio toxicity) 2ml too high volume – 0.50 – 1ml 	<p>Group 2. Injection Technique There was consensus as per protocol for items: 3, 4, 5, 10, 11 & 14 – 9 after discussion</p> <p>Item 1; As a result of discussion: • Concern -> variation in study centres risk management... could affect outcomes</p> <p>• Define brief Clinical assessment</p> <p>Item 2; As a result of discussion: • Up to 6 • Single injection possible (i.e. remove statement 'we anticipate two injections...')</p> <p>Item 6; as a result of discussion: • Skin -> Weal • Composition • 1% lidocaine • Via 25g needle into skin • + subcutaneous tissues at needle entry point</p> <p>• Rephrase; 1% lidocaine Via 25g needle into skin+ subcutaneous tissues at needle entry point</p> <p>Item 7; As a result of discussion: • 22gauge 10 -15 cm Quinke needle (depending on body Habitus)</p> <p>Item 8; As a result of discussion: Guide to joint cleft if possible intracapsular if not.</p> <p>Item 12; As a result of discussion: 2ml per joint (some will be peri articular some intra articular)</p> <p>Item 13; As a result of discussion: • Methylprednisolone, 20mg • Bupivacaine, 7.5 mg</p>	<p>Group 3. Injection Technique There was consensus as per protocol for items: 8, 10 & 11 after discussions items 1, 3, 5, 7 & 14 were agreed as protocol.</p> <p>Item 2 was discussed as two from the group found the protocol not acceptable. Following discussion, 2 Options ranked: Rank 1: (Y) As protocol + injection +/- Sacra... joint inject... if required Rank 2: (X) As protocol</p> <p>Item 4 was discussed as two from the group found the protocol not acceptable. Following discussion, 2 Options ranked: Rank 1: (F) As protocol + Prone position with pillows for lordosis. Rank 2: (E) As protocol</p> <p>Item 6 was discussed as three from the group found the protocol not acceptable. Following discussion, 3 Options ranked: Rank 1(Q): As protocol + Max 1ml per injection site. Rank 2(R): As protocol + Max 0.5ml per injection site. Rank 3 (P): As protocol</p> <p>Item 9 was discussed as two from the group found the protocol not acceptable. Following discussion, 4 Options ranked: Rank 1 (A): As protocol (parallax undefined). Rank 2 (D): As protocol but without parallax. Rank 3 (C): As protocol but parallax intermittent. Rank 4 (B): As protocol but parallax continuous</p> <p>Item 12 was discussed as three from the group found the protocol not acceptable. Following discussion, 4 Options ranked: Rank1(P): 2ml (as protocol), Rank2(Q): 1.5ml, Rank3(R): 1ml, Rank4(S): 0.5ml</p> <p>Item 13 was discussed as four from the group found the protocol not acceptable. Following discussion, 2 Options ranked: Local anaesthetic: 2 options were ranked: Rank 1 (A): L –Bupivacaine, Rank 2 (B): Bupivacaine. Steroid: 2 options were ranked: Rank 1 (X): Triamcinolone, Rank 2 (Y): Depo-Medrone (as protocol).</p> <p>Sub question (Item 13): 2 options were ranked: Rank 1 (U): As protocol with exclusion of systemic steroid use in last 3 months. Rank 2 (T): As protocol</p>	<p>Group 4. Injection Technique There was consensus as per protocol for items: 1, 3, 5, 6, 7, 8, 10 & 14. After discussions Items 2, 11, 12 & 13 were agreed as protocol.</p> <p>Item 4 was discussed as one from the group found the protocol not acceptable. Following discussion, 2 Options ranked: Rank 1: (B) As protocol plus measures to eliminate lumbar lordosis. Rank 2: (A) As protocol.</p> <p>Item 9 was discussed as two from the group found the protocol not acceptable. Following discussion, 2 Options ranked: Rank 1: (X) As protocol Rank 2: (Y) As protocol but needle does not have to be oblique</p>
<p>Plenary discussions and outcomes Results from the morning sessions were brought forward. Items: 1, 2, 3, 4, 5, 7, 8, 10, 11 & 14 were briefly discussed but there was general consensus on these.</p> <p>Item 6. was discussed 3 options were ranked: Rank 1(P): As protocol. Rank 2(Q): Max 1.0ml per injection site Rank 3 (R): Max 0.5ml per injection site</p>	<p>Notes: 44 Ballots two of which were spoiled (total included 42)</p> <p>Item 9. was discussed 3 Options were ranked: Rank 1 (A): As protocol. Rank 2 (C): As protocol adding intermittent Parallax. Rank 3 (D): No Parallax (remove from protocol). Notes: Adding continuous Parallax to protocol was discarded before ranking.</p>	<p>Item 12. 4 options ranked: Rank1 (P): 2ml per joint (as protocol). Rank2(R): 1ml. Rank3(Q): 1.5ml. Rank4(S): 0.5ml</p> <p>Notes: 41 Ballots, one noted not qualified to respond. 15 participants did not rank all four items just giving their top one or two. Item 13. Local anaesthetic. Two options voted on (Bupivacaine & lidocaine) both receive 6 votes.</p>	<p>Item 12 cont. Steroid 2 options were voted on: Triamcinolone (18 votes). Depo-Medrone (as protocol) (6 votes). Either (12 votes)</p> <p>Notes: There were 36 valid votes</p> <p>A number of results were confirmed post conference see below.</p>

the groups, lists were generated and items were then ranked. With the top ranked items going forward to the plenary discussions. However, in one group there was considerable discussion and the group agreed/ proposed a diagnostic pathway. This was taken forward to the plenary session. Key components of diagnostic assessment that were discussed in all groups include

increased pain on extension/rotation and extension/ lateral flexion and no pain on rising from flexion. In addition the following were considered: no radicular symptoms, no sacro-iliac joint pain on pain provocation testing, and flexion less painful than extension. Consensus was not reached on the day.

Injection technique – the process of therapeutic

interaarticular facet joint injection (Table 5): There were 14 aspects of the injection process for the groups to consider. In each group a number were considered acceptable without discussion although these varied between groups. All 14 aspects were brought to the plenary but 10 were discussed very briefly before consensus was reached. The following items prompted considerable discussion and were ranked: administration of local anesthetic and its composition, and confirmation of needle position, injectate volume, and injectate composition. Due to errors in ranking, we undertook post conference ranking of injectate volume and composition.

Best usual care (Table 6): All 4 of the best usual care group discussions followed a similar format. First, the

group discussed and voted on agreement/disagreement with the suggested protocol items. Moving forward, the groups then proposed and voted on new items for inclusion. Comprehensive packages were proposed in all groups and these were taken forward to the afternoon plenary session. While a consensus was reached regarding the key components to be included, some clarification was sought post conference.

Post Conference

After the consensus conference all rankings from the day were checked and verified. A number of errors were noted in all 3 design considerations.

Diagnosis: In order to confirm the diagnostic criteria for the study, the 45 clinically active delegates were

Table 6. Group and plenary results from Facet injection Study Consensus Conference looking at what is the optimal conservative management/rehabilitation for patients with low back pain where facet joints have been identified as a contributing source of symptoms

<p>Group 1, Best Usual Care package Initial agreements: result of vote agreeing/disagreeing with protocol items (yes = agree, no = disagree) A. Initial assessment (5 yes, 4 no) B. Individual session, number of sessions and duration (5 yes, 4 no) C. Manual Therapy (6 yes, 3 no) D. Home exercise (7 yes, 2 no) E. Cognitive approaches (5 yes, 4 no)</p> <p>Note: Individual (rather than group) sessions, the number of sessions in total (6), and the duration of each session; were combined in this group for the vote.</p>	<p>Group 2, Best Usual Care package Initial agreements: result of vote agreeing/disagreeing with protocol items (yes = agree, no = disagree) A. Initial assessment (5 yes, 0 no) B. Individual session, number of sessions and duration (8 yes, 1 no) C. Manual Therapy (6 yes, 3 no) D. Home exercise (8 yes, 1 no) E. Cognitive approaches (5 yes, 0 no)</p> <p>Note: Individual (rather than group) sessions, the number of sessions in total (6), and the duration of each session; were combined in this group for the vote.</p>	<p>Group 3, Best Usual Care package Initial agreements: result of vote agreeing/disagreeing with protocol items (yes = agree, no = disagree) A. Initial assessment (10 yes, 0 no) B. Individual session and number of sessions (8 yes, 2 no) C. Duration of sessions D. Manual Therapy (9 yes, 1 no) E. Home exercise (10 yes, 0 no) F. Cognitive approaches (10 yes, 0 no)</p> <p>Note: Individual (rather than group) sessions, the number of sessions in total (6), were combined in this group for the vote. The duration of each session was voted alone.</p>	<p>Group 4, Best Usual Care package Initial agreements: result of vote agreeing/disagreeing with protocol items (yes = agree, no = disagree) A. Initial assessment (10 yes, 0 no) B. Individual session and number of sessions (8 yes, 2 no) C. Duration of sessions (6 yes, 4 no) D. Manual Therapy (8 yes, 2 no) E. Home exercise (7 yes, 3 no) F. Cognitive approaches (8 yes, 2 no)</p> <p>Note: Individual (rather than group) sessions, the number of sessions in total (6), were combined in this group for the vote. The duration of each session was voted alone.</p>
<p>Result of votes for additional/excluded items in best usual care package Additional Items: Cognitive approaches</p>			
<p>Acceptance (9 yes, 0 no) Mindfulness (9 yes, 0 no) Option of written/electronic information (9 yes, 0 no)</p>	<p>No additional cognitive approaches put forward by this group</p>	<p>No additional cognitive approaches put forward by this group</p>	<p>Pain education Advice on managing 'flare up' Mindfulness/relaxation sessions A unanimous yes vote for all</p>
<p>Result of votes for additional/excluded items in best usual care package Additional Items: Physical Therapy</p>			
<p>A. Pain education (9 yes). B. manual movement assessment (7 yes). C. Activities of daily living (9 yes). D. Work/ergonomic advice (9 yes). E. Lifestyle changes (9 yes). F. Advice on changing symptoms (9 yes).</p> <p>3 options were ranked Rank 1: (X) 6 sessions 30/45 minutes over 6 weeks to 6 months. Rank 2: (Y) 5 x 45 minutes. Rank 3: (Z) As protocol</p>	<p>Addition of 'paced' to home exercise? (yes 8). Removal of passive movements? (6 no). To include initial therapy? (10 yes)</p> <p>4 options ranked (all sessions 30mins) Rank 1: (X) SOS session 1 month after final session. Rank 2:(Z) As protocol. Rank 3: (Y) Until therapy is effective or inappropriate. Rank 4: (W) SOS session 3 months after final session</p>	<p>Home exercise (10 yes). Combined aerobic exercise and whole body strength conditioning (10 yes) Combined movement approach (6 yes, 2 no). Manual therapy (8 yes)</p> <p>3 options were ranked Rank 1: (Z) As protocol. Rank 2: (Y) 1 X 45 minutes followed by SX 20 minutes. Rank 3: 5X 60 minutes (including assessment)</p>	<p>Positive/supportive therapist language (8 yes). Addition of TENS (8 yes). Addition of acupuncture (6yes, 3 no)</p> <p>5 options were ranked Rank 1: (C) 2-10 sessions X 30 minutes. Rank 2:(E) As protocol but up to 5 sessions. Rank 3: (D) 2-4 hours of therapist contact time. Rank 4: (A) As protocol. Rank 5: (B) 10X 60 minutes</p>
<p>Plenary discussions and outcomes Where possible top ranked or key results from the morning sessions were brought forward for discussion and consensus to the plenary session. However, a number of items included things that were outside of the project brief (e.g. endpoint is 3-months so 6-months not feasible). These were mentioned and adjusted accordingly.</p>	<p>The first discussions surrounded the possibility of including TENS and/or acupuncture in the package. A vote was taken to include then Result: TENS? (11 yes, 18 no) Acupuncture (3 yes 38 no)</p>	<p>7 options were discussed The two below were dropped 5 sessions, 45 minutes each 10 x 1 hour sessions</p> <p>5 options were ranked: Rank 1: (X) Up to 6X 45 minute sessions for 3 months</p>	<p>Rank 2:(E) As protocol but up to 5 sessions Rank 3: (D) 2-4 hours of therapist contact time Rank 4: (A) As protocol Rank 5: (B) 10X 60 minutes</p> <p>Final result for BUC package was confirmed post-conference.</p>

emailed to ask the following question:

We would like you to review the following text and confirm if the suggested clinical diagnostic criteria proposed for the study is “acceptable”? Stating “YES” or “NO”:

Increased pain unilaterally or 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 AND no radicular symptoms (defined as pain radiating below the knee) AND no sacro-iliac joint pain elicited using pain provocation testing.

Responses received: 23; Acceptable: YES = 22, NO = 1.

Injection technique: Following the consensus conference there was uncertainty about the injectate to be used in the study. Six options were sent, via email, to 27 delegates who had indicated they were responsible for injecting facet joints (e.g., pain consultants, anaesthetists). We received 11 responses. The results are presented in Table 7.

Best usual care: Confirmation of the number and duration of sessions was sought post conference. We emailed 15 delegates who were physiotherapists, extended scope practitioners, or clinical/health psychologists. Two alternatives, a) and b) below, were sent and delegates were asked to state a preferred option and to also say if they felt it was acceptable or not.

There were 12 responses.

One session of 60 minutes plus 5 sessions of 30 minutes (Preferred 9; Acceptable: 7 yes, 0 no)

Up to 6 sessions of 45 minutes each (Preferred 3; Acceptable: 6 yes, 1 no)

Among the 12 responses reported above, 2 responders answered both options were acceptable, one re-

sponder only provided a preference and did not state whether the options were acceptable, and 2 responders preferred option a and that this was the acceptable option.

The conference consensus and post conference clarifications were then edited into the protocol and operational manuals for the assessment for facet joint pain, injection of facet joints, and best usual care to be used in the feasibility study for the proposed clinical trial. The manuals are paraphrased in the following Figures: 7, 8, and 9.

DISCUSSION

We have established consensus from health professionals concerned with the treatment of facet joint pain in the UK on the clinical assessment of suspected facet joint pain, technique for therapeutic interaarticular injection of facet joints, and best usual care for use in a feasibility study for a proposed clinical trial of therapeutic interaarticular facet joint injections. The process was evidence based and open to all those with a professional interest in this topic, including lay participants, and undertaken in a transparent way. The use or not of interaarticular facet joint injection is controversial internationally, so consensus and transparency is essential for the design of the assessment, intervention, and control intervention for the proposed trial of interaarticular facet joint injections to ensure the results of the proposed trial are acceptable to the whole pain treatment community.

Transparency in the development and evaluation of health interventions is advocated. For example, there are now guidelines for describing assessment, intervention, and control intervention used in clinical trials (30,31). This is important for those using the results of the trial

Table 7. Post conference clarification process: Number of respondents indicating a preferred option and acceptable option for injectate showing preferred option and acceptability (yes or no).

Injectate options	Preferred option	Acceptable	
		yes	no
Triamcinolone 10mg/ Levobupivacaine 2.5mg	4	5	2
Triamcinolone 10mg/ Levobupivacaine 5.0mg	4	5	0
Triamcinolone 10mg/ Levobupivacaine 7.5mg	1	6	3
Triamcinolone 20mg/ Levobupivacaine 3.75mg	1	3	5
Triamcinolone 20mg/ Levobupivacaine 7.5mg	0	4	4
Triamcinolone 20mg/ Levobupivacaine 11.25mg	0	2	6

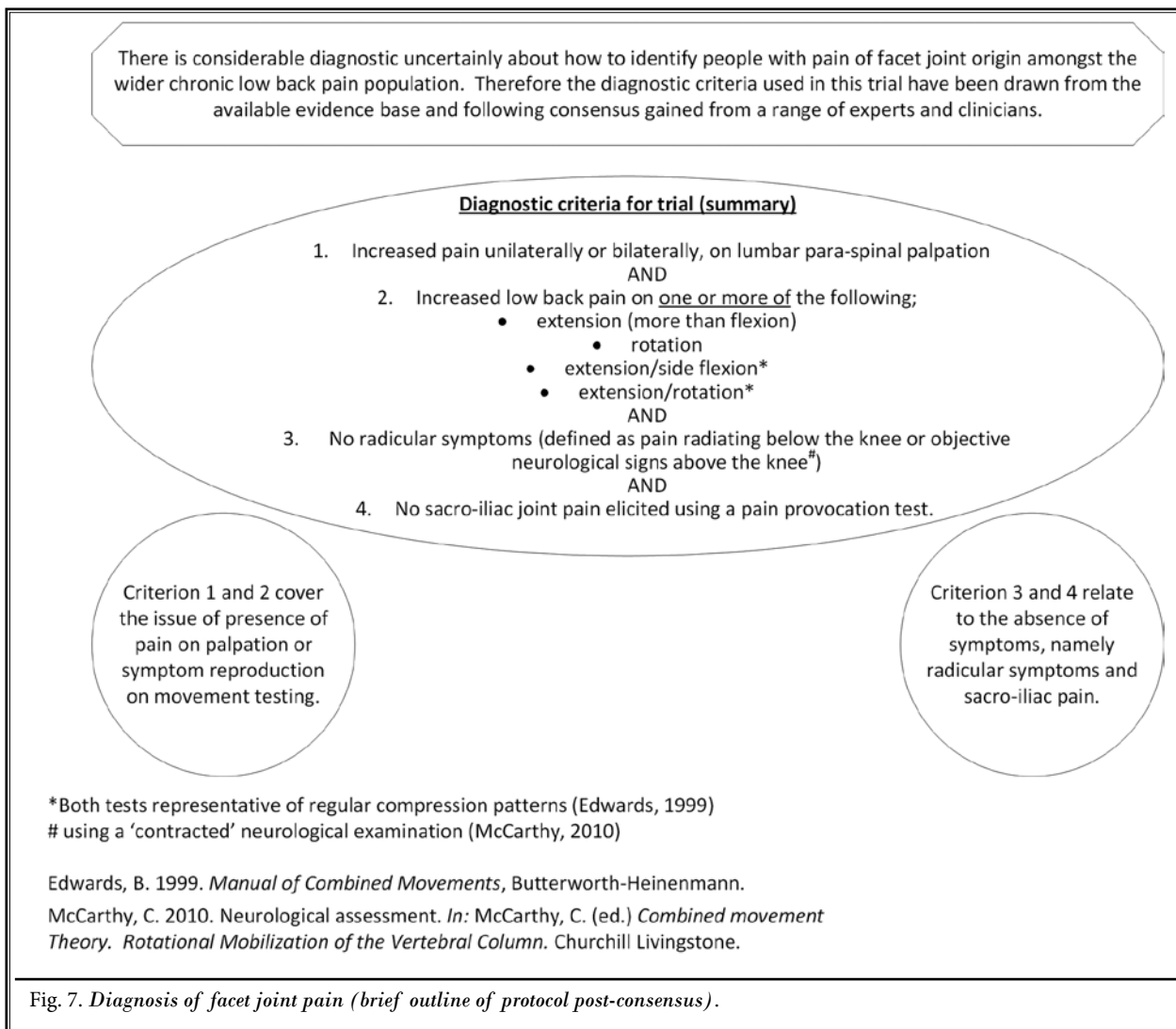
General comments: One responder did not answer acceptable yes/no

One responder answered yes acceptable Triam 10/Levo 7.5 “if using 0.75% Levobupivacaine”

One responder “good luck in finalising the protocol and getting through ethics”

One responder answered same injectate option as preferred and acceptable

One responder only gave an ‘acceptable’ option



in clinical practice or evidence synthesis. The Medical Research Council (MRC) Guidelines on the evaluation of complex interventions suggests that the evidence and theory on which intervention are based should be clear (31). Many funding bodies have a process for seeking public and expert contributions to deciding on the type of intervention that needs evaluation (32,33). However, the consideration of whether or not the most appropriate intervention is evaluated has broadly been left to funding review panels. Our consensus process has opened this up to clinicians and patients concerned with the intervention to ensure that they agree on the appropriateness of the intervention, including the assessment of the patient for the intervention and the control intervention. This process is particularly important for interventions that are already in clinical use.

The diagnostic criteria agreed at consensus generally included the small amount of evidence-based testing/assessment described in the literature. One exception was the exclusion of a clinical prediction rule by Laslett et al (34) who found that presence of 3 or more of the criteria: age > 50, symptoms best when walking, symptoms best when sitting, onset of pain is paraspinal, and positive extension/rotation test was 85% sensitive and 91% specific for facet joint pain. Another was the exclusion of the presence of a regular compression pattern using combined movement testing (an established simple, testing procedure, which purports to load the facet joint) (35,36). Although exploratory in nature, a small scale pilot study demonstrated 80% sensitivity and 74% positive predicative value of a regular compression pattern using combined movements in iden-

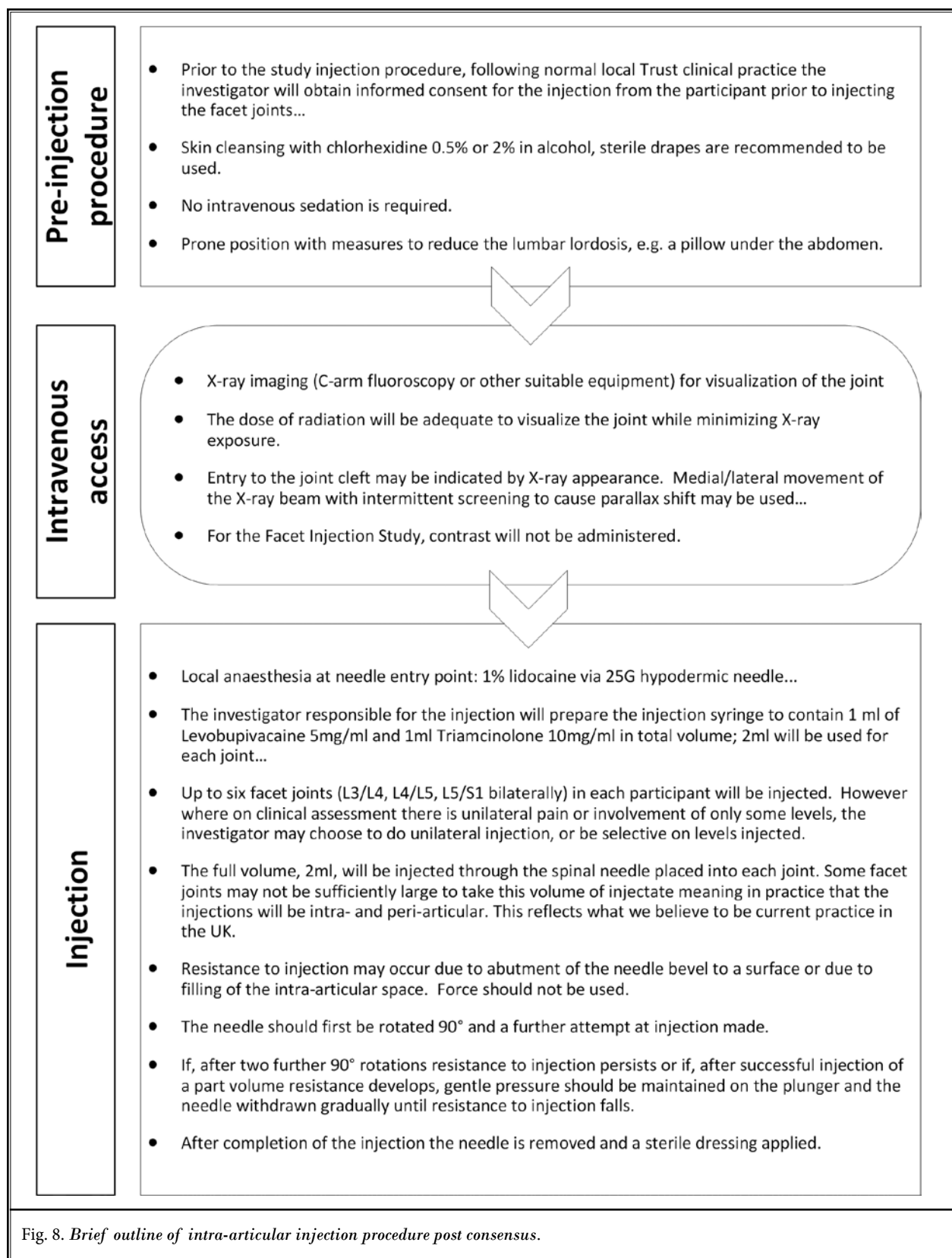
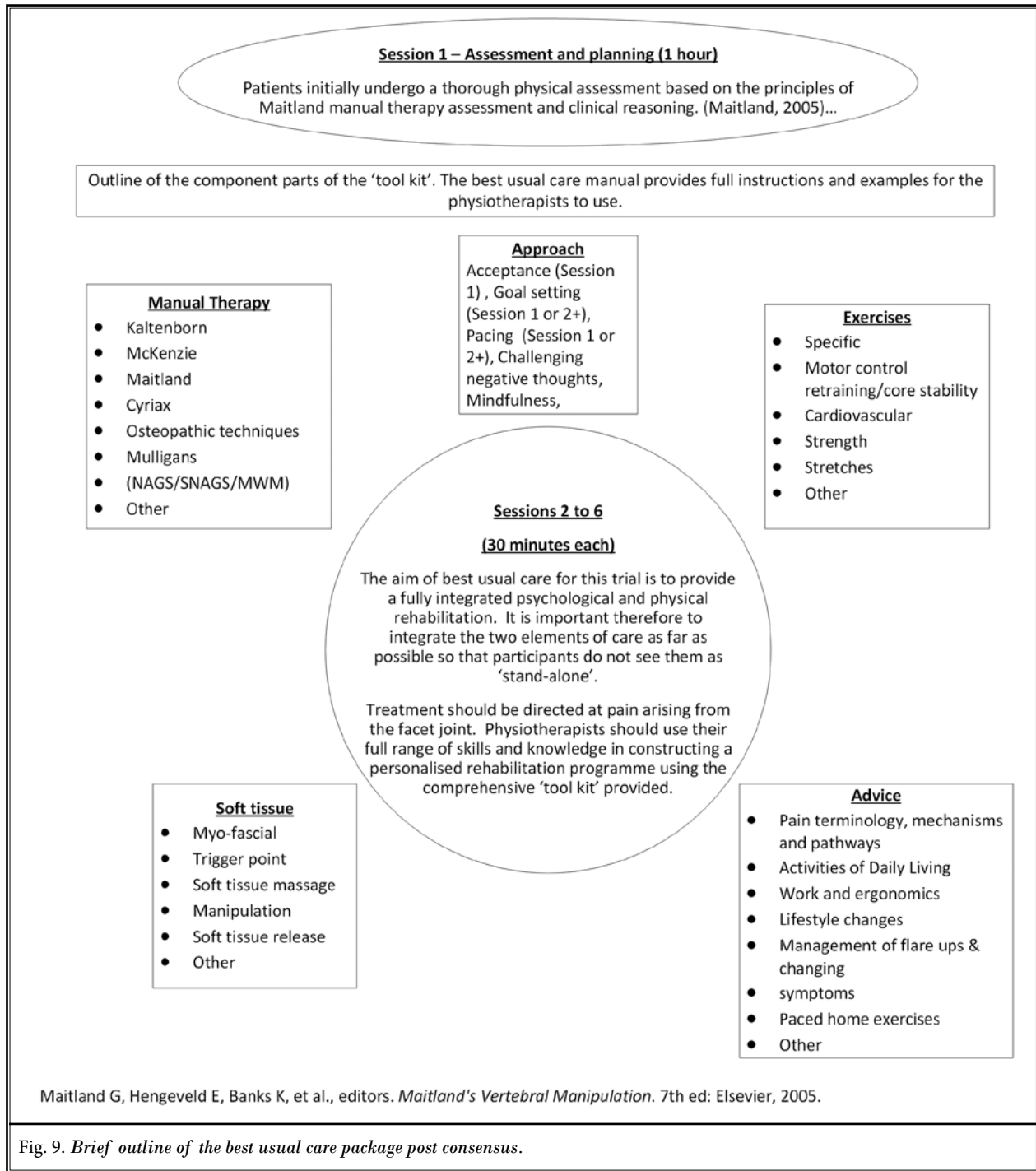


Fig. 8. Brief outline of intra-articular injection procedure post consensus.



tifying patients with facet joint mediated pain (37). However, although combined movements were not explicitly included, components of combined movements are included as part of the active testing procedure (Fig. 7; point 2).

The participants were asked to consider the technique for therapeutic interaarticular facet joint injection; the injection of a mixture of local anaesthetic and steroid to the vicinity of potentially painful facet joint(s) with the intention of reducing pain to facili-

tate compliance with the best usual care package. The resulting consensus details how the patient should be positioned, the type of needle and the approach to the target joint(s), and the type, dose, and volume of local anesthetic and steroid to be used. The consensus acknowledges the inherent uncertainties of exactly where the injectate ends up: intra-capsular or peri-articular. The consensus technique would be widely recognized as a safe and potentially effective method of therapeutic facet joint injection, reflecting current UK clinical practice. The consensus technique could be adopted by all participating units in a clinical trial. The technical details of the facet joint injection technique should not be a cause of dissent when considering the outcome of a definitive trial.

The evidence synthesis regarding the physical component of best usual care provided little in terms of robust research evidence in this specific low back pain population (i.e., facet joint pain). Therefore extrapolation from the wider low back pain literature was required in addition to searching of the key seminal texts within physical therapy. Consensus on best usual care, as identified in Figure 6, broadly represents the current evidence base around elements of manual therapy, motor control retraining, therapeutic exercise, soft tissue stretches/release, and postural and general advice. The key cognitive behavioral aspects identified were acceptance, goal setting, pacing, challenging negative thoughts, mindfulness, advice on daily activities, and homework sessions to reinforce the information. Once an individual has reached acceptance of their chronic pain and can move towards management rather than cure, research has shown that these individuals are more likely to practice positive, effective coping strategies, and report less pain, psychological distress, and physical and psychological disability (38). In line with current evidence and previous interventions for low back pain such as the BEST study (39), the key cognitive behavioral approaches delivered to participants were challenging unhelpful thoughts using cognitive re-structuring, goal setting, pacing, and management of flare ups which maps onto the consensus reached for the best usual care package. Unhelpful thoughts such as catastrophizing are associated with increased chronic pain and physical and psychosocial dysfunction including psychological distress (40,41). A discussion on mindfulness was also recommended to be part of the best usual care package. Mindfulness has been shown to have a positive impact on the experience of pain and the associated emotions and beliefs associated

with chronic pain such as stress, anxiety, and depression (42,43). In another intervention targeted at low back pain (the IMPACT study), communication skills were integrated into the cognitive behavioral approach as an important element of being able to deliver the intervention (44). Following the consensus conference, best usual care will integrate the cognitive behavioral package with the manual exercises, specifically looking at communication skills when discussing challenging unhelpful thoughts and goal setting.

Strengths and Limitations of the Study

Our consensus process was informed by systematically undertaken evidence reviews to ensure consensus participants were as informed as possible about current evidence and practice. It was inclusive with invitations widely distributed to all interested professional groups and to lay people. Although participants gave their time freely, none were out of pocket from attending. The consensus process used a well-established method adapted to the topic. By using confidential ranking, all participants were able to express their opinions. Facilitators were trained to ensure all participants were able to express views during discussion. The discussion allowed the opportunity for participants to learn about each other's clinical practice, exchange views, and persuade and be persuaded of alternatives.

The consensus process was limited to UK based clinicians and participants had to be free to attend in order to have a voice. Using a Delphi process would have enabled the engagement of international experts and could have included those interested but unable to attend on the day. However, there is no opportunity for sharing and discussion within a Delphi process. Packing discussion about the range of topics into one day was a challenge and resulted in time pressure on the plenary session, raising the possibility of participants not challenging issues as we neared the end of the conference. We underestimated the task of processing all the rankings so deployed too few people with skills to process the rankings. This resulted in a small number of errors. However, we had recorded every stage of the consensus process to ensure transparency and accuracy. Errors were identified and post conference consultation allowed those with expertise and interest to assist in finalizing the consensus.

Three systematic reviews informed this consensus process. The review looking for evidence for identifying patients with suspected facet joint pain (i.e., how best to diagnose lumbar facet joints as a source of pain

in chronic low back pain patients) was an update of a systematic review of tests to identify the found lumbar disc, sacro-iliac joint, or facet joint as a source of low back pain and found very little new data (45). The review related to the technique for injection of facet joints was complex and had multiple components, including a comprehensive review of published educational and training literature. This resulted in us having to consider 14 different aspects of the procedure. Our review of the peer reviewed literature focussed on extracting data on the techniques of injection used in primary studies; however, where this data was not reported, we did not have the resources to contact the authors for clarification. The review exploring the evidence around best usual was also complex in that it combined both the physical and the psychological components of rehabilitation packages in a variety of primary, secondary, and community settings, often these are exclusively reported. It is possible that our search strategies, like many, missed a small number of papers. In reviews of this nature it is unlikely that an occasional publication that we had failed to identify would materially change the conclusion.

A vast amount of information was provided to the delegates via the reviews. This can be something of a double edged sword in that we gave the delegates everything on the current state-of-the-art in these areas to help them make informed decisions. But equally the ability of the delegates to synthesize such a vast amount of information is hard to quantify.

CONCLUSION

This paper reports the process and results of a consensus process that engaged health professionals concerned with facet joint injections from across the UK. The results are being used in a feasibility study for a pragmatic RCT of therapeutic interaarticular facet joint injections in the UK. The consensus process has ensured that the assessment and intervention to be

trialed is one that is acceptable to the pain treatment community. This proposed trial will inform decisions on the funding or not of therapeutic interaarticular facet joint injection services, particularly in the UK. Other studies, drawing on the work done here, could test the effectiveness of other therapeutic interventions targeting lumbar facet joints.

Author contributions

Supported by HA, MC, SH, & FG MU was principally responsible for securing funding for the study. MU, TM, DE, SK and FG were involved in the conception and design of the consensus conference. TM, HA, HS, MC and KH prepared the evidence reviews. SK was responsible for the organisation of the conference including recruitment and data handling. DE collated and verified all results. TM, DE and FG drafted the manuscript supported by the other authors. The authors were all involved in the delivery of the conference. All authors have critiqued the paper for key academic content. MU is the chief investigator for the overall study. FG is the guarantor for the work reported here

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Conflict of Interest

MU was chair of the NICE back pain development group that produced the 2009 guidelines. None of the authors of the manuscript received any remuneration. Further, the authors have not received any reimbursement or honorarium in any other manner.

Intraarticular Facet Injections for Low Back Pain

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