Patients with moderate or severe pain at 3 months after total knee replacement (identified through either the Brief Pain Inventory or WOMAC pain scale)

Pain assessment and care allocation (nurse or extended scope practitioner led)

Red flags

Monitoring (nurse and self)

Pain improves

No further treatment

Pain persists or is problematic (self-completed questions)

Signs of infection, misalignment or instability

Surgeon

Surgery

Major depression

GP

Treatment or referral

Severe or interfering pain with indications of neuropathic or CRPS

Pain specialist

Treatment that might include neuropathic pain pathway or CRPS pathway as appropriate

Feedback and re-referral

Additional file 1: Schematic depiction of the draft STAR trial intervention
## Overview of STAR assessment clinic appointment, telephone follow-up and recommended treatment referral pathways

<table>
<thead>
<tr>
<th>Component</th>
<th>Overview of procedure</th>
<th>Recommended referrals</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>History and symptoms</strong></td>
<td>Patients are asked about the details of their pre-operative pain, knee replacement surgery, any post-operative complications, their recovery so far, expectations and satisfaction with surgery, general health, co-morbidities, other painful sites/conditions, analgesia used, and social circumstances. The onset, duration, nature, location and impact of the pain should be explored.</td>
<td>To be used in conjunction with results of other assessments to inform referral decisions.</td>
</tr>
</tbody>
</table>
| **Review of validated patient-reported outcome measures** | The patient is asked to complete the Brief Pain Inventory, PainDETECT, Douleur Neuropathique 4 and Hospital Anxiety and Depression Score immediately prior to seeing the Extended Scope Practitioner. These are reviewed during the assessment clinic. | **Brief Pain Inventory**  
To be used in conjunction with results of other assessments to inform referral decisions.                                                                                                                                   |
|                                    |                                                                                                                                                                                                                         | **PainDETECT and DN4**  
Patients with possible or probable on either questionnaire neuropathic pain component should be referred to GP to initiate neuropathic pain medications. If patients are already on neuropathic pain medications, then liaise with GP to: trial an alternative, increase the dose of pain medication, or refer to pain clinic for additional assessment and management. |
|                                    |                                                                                                                                                                                                                         | **Hospital Anxiety and Depression Score**  
Patients with probable or definite depression or anxiety should be referred to their GP. If already taking medication, liaise with GP to |
| **Knee palpation tenderness** | Patients are asked about areas of knee tenderness. Light palpation on all knee areas is performed to evaluate generalised hypersensitivity or hyperaesthesia. All knee areas are lightly rubbed to identify any sites of allodynia. The knee is palpated in a systematic manner for tenderness. | To be used in conjunction with results of other assessments to inform referral decisions.  
- Global tenderness may suggest a non-surgical origin for pain.  
- Focal tenderness may suggest a surgical origin for pain.  
- Hyperaesthesia or allodynia may suggest a neuropathic pain component or Complex Regional Syndrome. |
| **Wound assessment** | Assessment of healing, including ooze, redness, residual scab, retained stitch, dehiscence, ulceration, inflammation and hypertrophy is conducted. Skin temperature is evaluated using the backs of hands on both knees. Patients are asked about symptoms on fever, rigors, sweats, change in appetite, fatigue and generalised malaise. A blood sample is taken and sent to lab for testing of C-Reactive Protein levels. | Clinical suspicion for infection PLUS an elevated CRP level requires urgent surgeon referral.  
Minimal clinical suspicion for infection but raised CRP requires repeat of blood test approximately one month later. |
| **Range of motion** | Patient’s ability to perform a straight leg raise is assessed to give a guide to extensor mechanism and quadriceps function. Assessment of passive range of movement is made with a goniometer. | Extension deficit >10°, excessive hyperextension > 10° or flexion < 85° is sufficient for surgeon referral.  
Lack of active extension or a gross extensor lag may suggest a significant extensor mechanism problem, which would warrant a surgeon referral. |
| **Stability** | Knee stability is assessed with the patient lying supine on a couch with a single pillow under their head. If any test is positive, it is graded as 1+/2+/3+ (5mm/10mm/15mm). | 2+ or greater instability in any direction is sufficient for surgeon referral. |
A posterior draw test is performed. The knee is flexed as close to 90° as the patient can tolerate. Both hands are placed around the proximal tibia and a posterior force is applied to the proximal tibia.

Varus/valgus stability is assessed by supporting the knee and holding it flexed at 30°. To assess varus stability, one hand is placed on the medial aspect of the knee with the other around the lateral aspect of the ankle, and the knee stressed in a varus direction to assess the degree of opening. Valgus stability is assessed in the same way but with a hand on the lateral knee and medial ankle.

**Patellofemoral joint**

A patellofemoral compression test is performed. Thumbs are applied to the anterior patella and it is gently compressed towards the trochea groove. Whilst pressure is being applied, the patient is asked to carefully contract their quadriceps muscles. A positive test is discomfort elicited on quadriceps contraction.

Patellofemoral tracking is assessed through range of flexion and extension and peripatellar tenderness on palpation should give an indication of potential patellofemoral joint concerns.

Any concern for patellar maltracking or subluxation should prompt surgeon referral.

If the patellofemoral compression test is strongly positive, consider referral to surgeon for assessment of patellofemoral problems.

**Complex Regional Pain Syndrome (CRPS)**

History and examination findings prior to this stage of assessment will inform the possibility of a diagnosis of CRPS. Patients are assessed for pain that is spreading/radiating away from the joint, allodynia or touch sensitivity of the skin, swelling of the limb, colour changes or abnormal hair growth.

If any of the above signs or symptoms are present, this should be sufficient to raise suspicion of a potential CRPS diagnosis and formal criteria should be assessed. Extended Scope Practitioners are provided with the formal CRPS criteria.

If CRPS is suspected but the formal criteria are not met, patients should be referred to their GP to begin neuropathic pain medications, and recommend referral onto pain clinic if minimal or no response to analgesia. If formal CRPS
Criteria are met, patients should be referred to the pain services via their GP. Physiotherapy should be continued in either of the above scenarios, so as to encourage normal use and touch of the limb, and improvement in function despite the limitations of pain.

| Radiographs | Patients are x-rayed before attending the clinic appointment. For radiographic assessment a patient requires an AP weight-bearing long-leg alignment film, a true lateral and a patella skyline. It is important to ensure that the radiograph is not rotated. Coronal alignment is assessed by measuring the hip-knee angle on the long-leg film. This involves measurement of the angle from the centre of the femoral head to the distal centre of the femoral knee prosthesis and on from here to the centre of the ankle.

The radiographs should also be evaluated for any evidence of fracture, or concerns with sizing, fixation or position of the implants. If there is any gross concern regarding alignment, fracture, sizing, fixation or position of implants, referral to a surgeon should be considered. |

| Additional information relevant to the clinic assessment appointments | Further details of all assessments are provided in the intervention training manual and all results should be recorded on the standardised assessment proforma. All referrals should be considered in the wider context and referrals additional to those outlined in the intervention training manual can be performed depending on the needs of the individual patient. |

| Telephone follow-up | All patients who attend a clinic appointment have a maximum of six follow-up telephone consultations. This is to follow-up on the care that patients are receiving and to ensure that any referrals are being Not all patients with pain will meet criteria for, or indeed will need, onward referral. A proportion of patients will have pain that will |
undertaken. Additionally, further referrals can be made on the basis of these telephone follow-up consultations. Details of these telephone calls are recorded on a standardised proforma.

<p>| simply improve with time and it is entirely appropriate that such patients are followed up by telephone to monitor progress. If necessary, referrals can be made at a later date after telephone follow-up consultations. All patients who are being monitored without referral should have a telephone follow-up consultation at six weeks, three months and six months after their clinic appointment. |</p>
<table>
<thead>
<tr>
<th>Item number</th>
<th>Item</th>
<th>Where located</th>
</tr>
</thead>
</table>
| 1. | BRIEF NAME  
Provide the name or a phrase that describes the intervention. | Title page |
| 2. | WHY  
Describe any rationale, theory, or goal of the elements essential to the intervention. | Introduction |
| 3. | WHAT  
Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL). | Additional file 4 |
| 4. |  
Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities. | Additional file 5 |
| 5. | WHO PROVIDED  
For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given. | Additional file 4 |
| 6. | HOW  
Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group. | Additional file 4 |
| 7. | WHERE  
Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features. | Additional file 4 |
| 8. | WHEN and HOW MUCH  
Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose. | Additional file 4 |
| 9. | TAILORING  
If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how. | Additional file 4 |
| 11. | HOW WELL  
Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them. | Additional file 4 |
Patients with moderate or severe pain at 2 months after total knee replacement (identified through the Oxford Knee Score pain scale)

Pain assessment and care allocation by extended scope practitioner at 3 months after total knee replacement

Follow-up

Physiotherapy

Pain improves

No further treatment

Signs of infection, malalignment, stiffness, PFJ issue or instability

Surgeon with urgent referral

Assessment +/- Surgery

Depression or anxiety

GP

Treatment or referral

Pain specialist

Treatment that might include neuropathic pain pathway as appropriate

Severe or interfering pain with indications of Neuropathic Pain

GP to initiate medication

Pain reassessment after 6/52

No Improvement

Severe or interfering pain with indications of CRPS

GP to initiate urgent referral

Pain specialist Urgent if meets CRPS diagnostic criteria

Treatment that might include CRPS pathway as appropriate

Follow up and re-referral (all patients to be telephoned up to 6 times over 12 months)

Additional file 4: Schematic depiction of the final STAR intervention
### Additional file 5: Summary of the STAR trial intervention using TiDIER criteria

<table>
<thead>
<tr>
<th>TiDIER Criteria</th>
<th>Description of STAR trial intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name</strong></td>
<td>STAR (Support and Treatment After joint Replacement): A care pathway for patients with chronic pain after knee replacement</td>
</tr>
<tr>
<td><strong>Rationale</strong></td>
<td>Providing a clear entry point to services and delivering combination treatments that are matched to individual patients’ pain characteristics may lead to improved outcomes for patients with chronic pain after knee replacement.</td>
</tr>
</tbody>
</table>

#### Participant referral to intervention

<table>
<thead>
<tr>
<th>Participants receiving STAR intervention</th>
<th>Participants who are three months after primary total knee replacement for osteoarthritis and have pain in their operated knee, defined as a score of ≤14 on the 7 pain items of the Oxford Knee Score.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Referral procedure</td>
<td>Participant invited to attend a 1-hour individual outpatient hospital assessment clinic appointment with a physiotherapy Extended Scope Practitioner. Written letter to confirm appointment location, time and date.</td>
</tr>
</tbody>
</table>

#### Staff training for intervention delivery

<table>
<thead>
<tr>
<th>Training format</th>
<th>Three hour interactive training session and comprehensive intervention training manual.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who provided training</td>
<td>Consultant Orthopaedic Surgeon with specialist expertise in knee surgery and post-graduate qualification in chronic pain after knee replacement.</td>
</tr>
<tr>
<td>Who received training</td>
<td>Physiotherapy Extended Scope Practitioners delivering the intervention.</td>
</tr>
</tbody>
</table>

#### Assessment Procedure

<table>
<thead>
<tr>
<th>Materials required</th>
<th>Assessment clinic appointment: Goniometer, bed or plinth and pillow, venipuncture equipment, intervention training manual, patient-completed questionnaires, standardised assessment proforma, formal CRPS criteria.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Telephone follow-up: telephone, intervention training manual, standardised proforma.</td>
</tr>
<tr>
<td>Where</td>
<td>Assessment clinic appointment undertaken in a quiet hospital room. Room must have bed or plinth to allow patient to lie in supine position. Proximity to radiology department should be considered.</td>
</tr>
<tr>
<td>When</td>
<td>Single 1-hour assessment clinic appointment when participant is three months post-operative.</td>
</tr>
</tbody>
</table>
Telephone follow-up up to six times over 12 months to be arranged as deemed appropriate by the Extended Scope Practitioner.

<table>
<thead>
<tr>
<th>Tailoring</th>
<th>Every assessment conducted on every participant. Further assessment and onward referral arranged as appropriate (details in Additional file 4). Referral pathways can be tailored to individual patients and multiple referrals can be undertaken. Further referrals can be initiated as needed after follow-up telephone calls. Referrals not listed in the intervention training manual can be made depending on the needs of the patient.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modifications</td>
<td>Intervention refined during intervention development work (see Additional files 1 and 2)</td>
</tr>
</tbody>
</table>

### Intervention Fidelity

<table>
<thead>
<tr>
<th>Training</th>
<th>Training signature logs completed after attendance at training session.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention delivery</td>
<td>Training emphasises adherence to the intervention training manual. During the randomised controlled trial, Quality Control (QC) visits to staff delivering the intervention at every site will be undertaken by a member of STAR team. QC visits will include observation of the delivery of the assessment clinic appointment and follow-up telephone calls. A minimum of one STAR assessment per Extended Scope Practitioner will be observed. The observer will complete QC assessment form to record accuracy of completion of trial paperwork; checklist of assessment of risk factors; whether referrals were warranted and actioned appropriately. Any areas requiring further training will be highlighted and actioned. QC form will be signed and dated by assessor and Extended Scope Practitioner.</td>
</tr>
</tbody>
</table>