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# BMJ Open

## Implementation of an evidence-based model of care for acute low back pain in emergency departments: Protocol for the SHaPED trial

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Manuscripts

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3 **Implementation of an evidence-based model of care for acute low back pain in**  
4 **emergency departments: Protocol for the SHaPED trial**  
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## ABSTRACT

**Introduction:** Patients with low back pain often seek care in emergency departments, but the care is often sub-optimal. The problem is that many patients receive unnecessary or ineffective care, and at the same time miss out on the basics of care, such as advice on how to self-manage the condition. This pattern of care has important consequences for patients (poor health outcomes) and for the healthcare system (expensive and inefficient). We hypothesised that the implementation of an evidence-based model of care will improve the care delivered to patients with acute low back pain presenting to emergency departments.

**Methods and analysis:** A stepped wedge cluster randomised controlled trial will be conducted to implement and evaluate the use of the Agency for Clinical Innovation (ACI) model of care for acute low back pain at four emergency departments in New South Wales, Australia. Acute low back pain presentations will be identified using SNOMED codes. The 4-week intervention period, targeting emergency department clinicians, will comprise educational materials and seminars, and an audit and feedback approach. The effectiveness of the intervention will be assessed by comparing the post-intervention period with the retrospective baseline control period prior to implementation. Outcomes are routinely collected measures of imaging referrals (primary outcome), opioid prescription, and inpatient admission, which will be extracted directly from participating emergency departments' electronic record systems.

**Ethics and dissemination:** The study received ethical approval from the Sydney Local Health District (RPAH zone) Ethics Committee (04/2017). The results of this study will be published in peer-reviewed journals and presented at international conferences.

**Trial registration number:** Australia New Zealand Clinical Trials Registry: ACTRN12617001160325.

**Strengths and limitations of the study**

- This is a novel implementation trial looking at reducing unnecessary tests and treatments for acute low back pain in emergency departments
- The stepped wedge design is particularly suited to interventions aiming to improve healthcare systems as all sites receive the intervention; intervention effects are estimated from within-emergency department differences while controlling for time trends
- The use of routinely collected measures reduces the burden of data collection in the emergency departments
- Incorporation of only four clusters (emergency departments) in the trial may limit generalisability
- The absence of patient-outcome measures may limit the understanding of the effects of the implementation on patient outcomes

## INTRODUCTION

### Background and rationale

Low back pain is a common presenting complaint in emergency settings. In 2015-16 alone, there were 104,072 low back pain presentations to emergency departments in Australia, placing this condition among the top 10 reasons for emergency visits.<sup>1</sup> This condition is also a common reason for emergency department presentations across the globe, accounting for 4.4% of all presentations.<sup>2</sup> Unfortunately, many patients receive the wrong care for their low back pain in the emergency department. Examples of low-value care include unnecessary imaging, liberal use of opioid analgesics, and unnecessary admission to hospital, which provide little or no benefit, and may cause harm.

Multiple clinical guidelines exist for the management of low back pain in primary care.<sup>3,4</sup> Although it is unclear whether these guidelines should be applied in the emergency department, much of their recommendations may be relevant to emergency physicians and are often used to guide their practice.<sup>5</sup> However, the mixture of providing inappropriate care and failing to provide appropriate care in the emergency department is a clear indication that healthcare is not following clinical guidelines. For instance, about 30% of patients with non-specific low back pain receive imaging in the emergency department,<sup>6</sup> when guidelines explicitly recommend no imaging for these cases. Imaging in the absence of suspected serious pathology does not improve patient outcomes,<sup>7</sup> and can potentially cause harms.<sup>8-10</sup> Against guideline advice, around 62% of low back pain patients are prescribed opioids in the emergency department,<sup>11</sup> although efficacy in pain relief has not been established for acute low back pain<sup>12</sup> and side effects are often serious,<sup>13</sup> including dependence, overdose and death. Another issue is the increasing rate of hospital admissions. More than one third of low back pain presentations to the emergency department lead to the patient being admitted to hospital,<sup>6</sup> where care is no more effective than what could be provided in primary care.

The significant deviations from evidence-based recommendations occurring in Australian emergency departments makes them an appropriate setting to trial an intervention based on improving care for acute low back pain. The Agency for Clinical Innovation (ACI) has recently launched a model of care for acute low back pain that could be applied in both primary care and emergency department settings.<sup>14</sup> The ACI model of care was developed in collaboration with policy makers, clinicians, consumers and researchers, and distils the high quality evidence in this area to formulate key messages for practice. Briefly, the model

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3 provides different care pathways according to a classification based on a diagnostic triage<sup>15</sup>  
4 (non-specific low back pain, low back pain with leg pain, suspected serious spinal  
5 conditions). Then, risk stratification<sup>16</sup> is used to guide the amount and type of treatment  
6 provided; including personalised evidence-based health education and treatment. Lastly,  
7 follow-up reviews are scheduled to monitor individuals' progress. Passive dissemination of  
8 guidelines, such as the ACI model of care, is unlikely to change practice. We are proposing a  
9 multi-faceted strategy to implement and evaluate the ACI model of care to see if this  
10 improves care for acute low back pain at emergency department settings.  
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## 16 17 **Objectives**

18 The overall aim of the Sydney Health Partners Emergency Department (SHaPED) trial is to  
19 implement and evaluate the ACI model of care for acute low back pain. The outcomes of the  
20 trial reflect the key messages in the model: 1) patients with acute non-specific low back pain  
21 do not require imaging; 2) where medicines are used, simple analgesics should be the first  
22 option; 3) patients with acute non-specific low back pain should be managed as outpatients.  
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### 28 *Primary objective*

29 The primary objective of this study is to evaluate if implementation of the ACI model of care  
30 for acute low back pain improves care provided in the emergency department.  
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### 35 *Secondary objectives*

36 The secondary aims of the study are:

- 37 1. To determine the cost-effectiveness of the ACI model of care for acute low back pain  
38 compared with current practice.
- 39 2. To determine the barriers and facilitators to the implementation strategy of the ACI  
40 model of care for acute low back pain.  
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## 46 **METHODS AND ANALYSIS**

### 47 **Study design**

48 SHaPED will use a stepped wedge cluster randomised controlled trial design.<sup>17</sup> In this study  
49 design, clusters are randomised to cross from the control period (i.e., unexposed to  
50 intervention) to the intervention period at regular intervals ('steps') until all clusters have  
51 crossed to the intervention under evaluation. This design is particularly suited to interventions  
52 aiming to improve healthcare systems as all groups eventually receive the intervention.  
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3 Moreover, the process allows for comparison with control sites that have not yet implemented  
4 the intervention. For this protocol, we completed the Consort 2010 statement checklist  
5 extension for cluster randomised trials.<sup>18</sup>  
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9 In the SHaPED trial, after a retrospective baseline observation control period of 12 months  
10 prior to randomisation, the intervention will be sequentially rolled out, with a new emergency  
11 department receiving the intervention every four weeks, until all participating emergency  
12 departments have received the intervention. After the implementation of the ACI model of  
13 care, the emergency departments will continue using the pathways of care outlined in the  
14 model until the end of the trial (Table 2).  
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### 19 20 21 **Study setting**

22 The emergency departments of one rural and three urban hospitals in NSW, Australia will  
23 participate in the study: Royal Prince Alfred Hospital, Concord Repatriation General  
24 Hospital, Canterbury Hospital, and Dubbo Base Hospital. The SHaPED trial has been  
25 approved (X17-0043) by the Ethics Review Committee of the Sydney Local Health District  
26 (RPAH zone), and by the Chief Executive of each participating institution. The trial was  
27 registered with the Australia New Zealand Clinical Trials registry: ACTRN  
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### 34 35 36 **Participants**

37 Participants included in this study will be emergency clinicians, such as physicians, nurses,  
38 and physiotherapists, who routinely manage patients presenting to emergency departments  
39 with a primary complaint of acute low back pain (lasting less than 3 months) or acute  
40 exacerbation of chronic low back pain. We will use codes from the Systematised  
41 Nomenclature of Medicine – Clinical Terms – Australian version, Emergency Department  
42 Reference Set (SNOMED CT-AU [EDRS])<sup>19</sup> to identify acute low back pain presentations.  
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48 Potential clinician participants will be invited by the local investigators at each emergency  
49 department and will receive a Participant Information Statement. Research staff will verbally  
50 explain the information provided in this document to fully inform potential clinician  
51 participants of the risks and benefits of participation. In addition, the research staff will be  
52 available to answer any questions in order to ensure that potential clinician participants fully  
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3 understand the implications of their decision. A written Participant Consent Form will be  
4 obtained from all participating clinicians prior to randomisation.  
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### 7 8 **Randomisation**

9 Before the beginning of the implementation process, the four hospitals will be randomly  
10 allocated the step when the intervention will commence at their emergency department.  
11 Randomisation will be conducted using computer-generated random numbers. Only the  
12 research team will be aware of cluster allocation.  
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### 16 17 **Implementation intervention**

18 A framework has been proposed to facilitate the implementation of research evidence into  
19 clinical practice, known as The Knowledge-to-Action Process.<sup>20</sup> This framework links the  
20 various types of research enquiry with the key steps in the research translation cycle. The  
21 process consists of the knowledge creation cycle and the action cycle, and involves end users  
22 of research (e.g., policymakers, clinicians and patients) to facilitate engagement with the  
23 implementation strategy. We will use this framework to develop a tailored intervention  
24 strategy to implement the ACI model of care at the participating emergency departments.  
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31 Engagement of local opinion leaders that are respected and influential at each site is an  
32 important element in promoting and maintaining local interest in the implementation process.  
33 Thus, implementation will begin with visits to each participating emergency department to  
34 establish collaborations and approvals, and to further assess organisational issues and  
35 potential barriers to the implementation program, such as intake and flow of patients with low  
36 back pain, assessment of current practices, acceptability of new model, and specific roles of  
37 emergency clinicians. We will map existing models of care at each emergency department  
38 that are used to guide management of patients presenting with acute low back pain. Then, we  
39 will work with local clinical staff to incorporate important features of existing models to the  
40 recommendations and principles outlined in the ACI model of care.  
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49 A multi-faceted intervention package will be used to implement the ACI model of care at the  
50 emergency departments. Briefly, the initial 4-week intervention will consist of printed and  
51 electronic educational materials, educational seminars and educational outreach, website  
52 support, posters, and an audit and feedback approach. Clinician participants will receive a  
53 copy of the model and other printed educational materials, as well as access to additional  
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3 online support tools. Experienced clinicians, research staff, and local opinion leaders will  
4 deliver the interactive educational seminars and educational outreach. An audit and feedback  
5 approach focussed on the outcomes of the study will also be used to enhance our  
6 implementation program. A detailed description of the implementation plan for the SHaPED  
7 trial can be found in Supplementary Appendix 2.  
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12 The implementation intervention will be tailored for each site by adapting knowledge  
13 resources (e.g., printed decision aids, patient resources) to the local context and by working  
14 with local opinion leaders (e.g., directors of emergency department) to address potential  
15 barriers to implementing the ACI model of care. These instructions, measures, and training  
16 materials will be hosted online during the implementation phase on the University of Sydney  
17 website. Due to the nature of the intervention, it will not be possible to blind clinician  
18 participants to the intervention.  
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### 25 **Sample size**

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27 Based on the effect size of 10% absolute reduction (from 30%<sup>6</sup> to 20%) in imaging referrals,  
28 combined with an alpha of 0.05 and assuming an Intraclass Correlation Coefficient (ICC) of  
29 0.1, a total number of 1,920 low back pain presentations (on average 480 per cluster) to  
30 emergency departments is needed for this stepped-wedge cluster trial with 80% power. A  
31 preliminary analysis revealed that there were over 2,500 low back pain presentations to the  
32 participating emergency departments in 2015-16, showing feasibility of this trial.  
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### 38 **Outcome Measures**

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40 Clinician participants will complete a baseline questionnaire, including demographic  
41 questions. They will also be asked to indicate whether they have special interests in low back  
42 pain or musculoskeletal medicine, and if they had attended previous continuing medical  
43 education or postgraduate training on low back pain management. The baseline questionnaire  
44 also includes the Back Beliefs Questionnaire,<sup>21</sup> and questions<sup>22</sup> about clinicians' knowledge  
45 and attitudes towards low back pain management. The outcomes to evaluate the effectiveness  
46 of the ACI model of care for acute low back pain are routinely collected emergency  
47 department measures.  
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#### 54 *Primary outcomes:*

- 55 • Proportion of patients receiving any imaging (yes/no)  
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*Secondary outcomes:*

- Proportion of patients receiving advanced imaging (CT or MRI = yes, x-ray or no imaging = no)
- Proportion of patients receiving prescription or administered analgesic medications (topical, oral, injection):
  - Simple analgesics (e.g., paracetamol)
  - Non-steroidal anti-inflammatory drugs (NSAIDs)
  - Muscle relaxants
  - Weak opioids
  - Strong opioids
  - Neuropathic pain medicines
  - Other
- Time in emergency department (triage time to discharge or admission time)
- Proportion of patients admitted to:
  - Emergency medical unit
  - Rheumatology department
- Proportion of patients referred to surgical specialist (referral for a post-discharge surgical consultation by the emergency department)
- Proportion of patients re-presenting to any emergency department within 28 days
- Proportion of patients re-admitted to any hospital within 48 hours
- Total health system costs (including intervention costs and health service utilisation costs)

Medicines will be classified according to the Anatomical Therapeutic Chemical (ATC) classification system (Table 3). The ATC classification is recommended by the World Health Organisation and is widely used internationally in drug utilisation studies.

**Data collection methods**

In the week prior to the intervention program and in the week after the 4-week intervention period, clinician participants will be asked to answer the questionnaires. Outcome measures will be extracted every week directly from participating hospitals' electronic record systems, such as the Sydney Local Health District Targeted Activity and Reporting System (STARS). STARS is an electronic system which monitors service utilisation across the SLHD hospitals.

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3 Data collection through hospitals' electronic systems will avoid additional workloads within  
4 the emergency departments.  
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8 Research staff, blinded to the intervention allocation, will be responsible for accessing the  
9 hospitals' electronic systems and for extracting relevant information for our study. Data will  
10 be securely stored in password-protected spreadsheets and transferred to appropriate  
11 statistical software for analysis. Spreadsheets will be regularly scrutinised for omissions and  
12 errors. Data will be archived at the Sydney School of Public Health, The University of  
13 Sydney for 15 years, after which data will be destroyed.  
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### 18 19 **Statistical methods**

20 Data analysis will be performed according to an intention-to-treat analysis, i.e. clusters will  
21 be analysed according to their randomised crossover time irrespective of whether crossover  
22 was achieved at the desired time. Firstly, we will investigate temporal trends in healthcare  
23 outcomes across the 12-month baseline observation period. In the situation of an underlying  
24 temporal trend, we will only include data for the previous three months as the baseline  
25 observation period. In our primary analysis, the 4-week intervention period will be excluded,  
26 but a secondary exploratory analysis will be performed including the intervention period into  
27 the intervention group. For the primary outcome analysis, logistic regression models with a  
28 random effect for cluster, a fixed effect indicating the group assignment of each cluster at  
29 each step, and a fixed effect of time (each step) will be used. A detailed statistical analysis  
30 plan will be developed prior to unblinding. Data will be analysed using SAS version 9.1.3  
31 (SAS Institute Inc., Cary, NC).  
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### 42 **Economic evaluation**

43 An economic evaluation of the ACI model of care compared with current practice will be  
44 undertaken from the health system perspective. Firstly, we will measure the costs related to  
45 the delivery of the implementation intervention (i.e., training component, staff time, printed  
46 resources). Then, the costs related to health resource utilisation will be measured via data  
47 captured by the hospitals' electronic record systems. Costs will be valued based on  
48 government charges, using publicly available data. All costs will be reported in Australian  
49 dollars. Where necessary, costs will be converted to 2017 prices using the health consumer  
50 price index published by the Australian Bureau of Statistics. The incremental cost-  
51 effectiveness ratio will be presented as the incremental cost per patient avoiding imaging (any  
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3 and advanced), medicine prescription, and hospital admission. Sensitivity analyses will be  
4 conducted to examine uncertainty in key parameters.  
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### 7 8 **Process evaluation**

9 A process evaluation will be conducted in order to provide an indication of which elements of  
10 the implementation intervention are effective and worthwhile. Clinician participants' reviews  
11 about the content of educational materials will be analysed, as well as their knowledge in  
12 managing low back pain before and after the intervention. Potential barriers and facilitators  
13 will be described.  
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### 18 19 **ETHICS AND DISSEMINATION**

20 The SHaPED trial received ethical approval from the Sydney Local Health District (RPAH  
21 zone) Ethics Committee, Sydney, Australia (04/2017). Our hypothesis is that implementation  
22 of the ACI model of care will improve care in participating emergency departments for  
23 patients presenting with acute low back pain: specifically decreasing the rates of imaging  
24 referrals, opioid prescription, and hospital admission. If the trial results are positive we will  
25 build upon our existing strong relationships with the ACI, Sydney Health Partners, and the  
26 Local Health Districts to support implementation of the model of care in other emergency  
27 departments across NSW. As a branch of the NSW Ministry of Health, the ACI will be well  
28 positioned to facilitate transferability of findings. We will also disseminate the results of the  
29 trial at conferences and in scientific journals and we will continue our successful approach of  
30 using the media to reach a lay audience and health consumers. The study resources will be  
31 made freely available on relevant websites so that jurisdictions beyond NSW can adopt the  
32 implementation strategy outlined in this study.  
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**Contributors:** GCM, BR, CN, RB, IH, and CM conceptualised the research design, drafted the research protocol, and are coordinating the project team. JE, ER, RF, DLC contributed to the design of the study protocol, and are lead site investigators. MO, RK, and HS are responsible for the acquisition of data. MV, NM, KM, RD, RL, MJ, RS, NA, NM, MF, PF, and CL contributed to funding applications. LB advised on the trial design and was responsible for the sample size calculation and statistical analysis methods. KH was responsible for the design of the economic evaluation. KM was responsible for the design of the process evaluation. MO, RP, MC, MM, DC, DH, and LB are site investigators contributing to the implementation of the model. All authors contributed to refinement of the study protocol and approved the final manuscript.

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**Competing interests:** None declared.

**Patient consent:** Consent of the clinician participants will be obtained.

**Ethics approval:** The study received ethical approval from the Sydney Local Health District (RPAH zone) Ethics Committee, Sydney, Australia (04/2017).

**Provenance and peer review:** Not commissioned; externally peer reviewed.

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**Table 1.** The key principles of the ACI model of care for acute low back pain

Principle 1	Assessment: history and examination
Principle 2	Risk stratification
Principle 3	Patient education
Principle 4	Active physical therapy encouraged
Principle 5	Begin with simple analgesic medicines
Principle 6	Judicious use of complex medicines
Principle 7	Cognitive behavioural approach
Principle 8	Only image those with suspected serious spinal pathology
Principle 9	Pre-determined times for review
Principle 10	Timely referral and access to specialist services

Source: NSW Agency for Clinical Innovation. Management of people with acute low back pain: model of care. Chatswood; NSW Health; 2016. 39 p, available at: <https://www.aci.health.nsw.gov.au/resources/musculoskeletal/management-of-people-with-acute-low-back-pain/albp-model>

**Table 2.** SHaPED trial design

Steps (clusters)	Year 1												Year 2						
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7
ED 1	Light	Light	Light	Light	Light	Light	Light	Light	Light	Light	Light	Light	Light	Dark	Dark	Dark	Dark	Dark	Dark
ED 2	Light	Light	Light	Light	Light	Light	Light	Light	Light	Light	Light	Light	Light	Dark	Dark	Dark	Dark	Dark	Dark
ED 3	Light	Light	Light	Light	Light	Light	Light	Light	Light	Light	Light	Light	Light	Dark	Dark	Dark	Dark	Dark	Dark
ED 4	Light	Light	Light	Light	Light	Light	Light	Light	Light	Light	Light	Light	Light	Dark	Dark	Dark	Dark	Dark	Dark

- 12-month retrospective control period
- 4-week initial intervention period
- Clusters continue with intervention
- 3-month follow-up period

For peer review only

**Table 3.** Medicines per ATC classification

<b>Group</b>	<b>ATC code</b>
Analgesics	N02B
NSAIDs	M01A M02AA
Opioid single	N02A (except for combinations listed below)
Opioid combinations	N02AA51 Morphine, combinations N02AA55 Oxycodone, combinations N02AA59 Codeine, combinations excluding psycholeptics N02AC54 Dextropropoxyphene, combinations excluding psycholeptics N02AX52 Tramadol, combination
Neuropathic pain medicines	N03 N06A

ATC, Anatomical Therapeutic Chemical. NSAIDs, Non-steroidal anti-inflammatory drugs

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2  
3 **Supplementary Appendix 1. The SHaPED trial investigators**  
4  
5

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## Supplementary Appendix 2. Implementation strategy and intervention description

The implementation plan for the SHaPED trial has been adapted from Jabbour et al.<sup>23</sup>

### 1. Create implementation team:

- a) Obtain support from clinical leads and administration heads at the four emergency departments. Formalise a partnership agreement between institutions.
- b) Recruit and engage study champions at each emergency department. Team members to include: emergency physicians, physiotherapists, nurses, managers, and clinical educators.
- c) Develop a working group and form a steering committee at each emergency department to provide oversight on implementation progress.
- d) Establish meeting schedule: local steering committee to meet twice a week and report to study supervisors every week during the implementation period.

### 2. Assessment:

- a) Review and discuss the existing models of care for acute low back pain at the four emergency departments and recommend adaptation to facilitate adoption of the new model.
- b) Conduct an environmental assessment and identify typical pathway of care for a patient presenting with low back pain at each emergency department.
- c) Identify practices and processes that require development or change in order to support the implementation strategy.
- d) Identify internal and external stakeholders who will be impacted by the new model and therefore require education and support to implement it.

### 3. Plan strategy for change

- a) Identify leadership support required for implementation phase.
- b) Identify and engage influential clinical champions who will effectively drive change.
- c) Revise or develop policies as needed.
- d) Develop a knowledge translation strategy to support practice change, such as shared staff meetings, educational rounds, peer-to-peer mentoring.
- e) Identify factors that will support practice change, such as engaging all potential stakeholders, scheduling champions and clinicians to enable attendance at meetings and face-to-face education sessions, facilitating the development of relationships between

1  
2  
3 emergency physicians and other clinical staff, conducting audits or monitor specific data  
4 indicators that will support practice change.  
5

- 6 f) Identify factors that may create a barrier for practice change in the emergency department,  
7 including attitudes and beliefs about low back pain management, and lack of clinician  
8 expertise/comfort to treat this population.  
9  
10 g) Develop strategies to manage barriers, such as communication, education, opportunities to  
11 develop relationships within and between clinicians and service provider.  
12  
13  
14

#### 15 4. Implementation:

##### 16 a) Provide Clinician information package:

- 17  
18  
19 • Deliver printed copies of the ACI Model of care (full version and executive summary) to  
20 clinician participants.  
21  
22 • Create a list of “red flags” to screen for serious pathologies from the ACI Model of care  
23 and deliver a printed version to clinician participants.  
24  
25 • Create posters outlining the ‘10 principles’ of the ACI model of care, as well as the  
26 clinical pathways and place them at key locations of each participating emergency  
27 department.  
28  
29 • Inform clinician participants about and provide them access to online videos and other  
30 electronic educational materials to recommend patients with acute low back pain at  
31 discharge.  
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##### 36 b) Provide patient information package:

- 37  
38  
39 • Encourage clinician participants to provide a printed copy of the ACI Consumer  
40 Information document to patients with acute low back pain during emergency department  
41 visit.  
42  
43 • Where the majority of the patient population do not speak English, encourage clinician  
44 participants to provide a copy of the Emergency Care Institute (ECI) Patient Factsheet for  
45 acute low back pain (available in six languages).  
46  
47 • Create posters outlining four myths of acute low back pain management and placed them  
48 at the reception area of each emergency department.  
49  
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51

##### 52 c) Deliver clinician education:

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- Educational seminars will be delivered by an experienced clinician (Dr Chris Needs) at week 1 of the intervention period. Booster sessions in the first week will also be conducted by local investigators (e.g., directors of emergency department, clinical educators) as required, as well as in weeks 2-4.
- The educational seminars will be conducted primarily during the existing regular clinical staff meetings, but additional sessions will be scheduled to reach all clinician participants. The format of the seminars consists of a mini-lecture and interactive group discussions and will last for 20-40 minutes.
- During the educational seminars, clinician participants will be trained on history taking and examination of patients with acute low back pain, on how to use SNOMED diagnosis codes, and will be encouraged to follow the recommendations in the ACI model of care to manage these patients, with focus on the key outcomes of this study (i.e., imaging, opioids, and inpatient admission).
- During weeks 1-4, individual meetings with clinician participants will be scheduled as required to cover the key messages and principles outlined in the ACI model of care. There will be at least one educational outreach visit to each clinician in weeks 1-4 and they can request additional if they have concerns or problems. Clinicians can also seek advice by email.

d) Develop audit and feedback focussed on study outcomes

- Each emergency department and clinician participant will receive at the first educational seminar session emergency department level feedback on the 12-month retrospective data performance against the outcomes of this study (e.g., imaging, opioid prescribing, inpatient admission).
- This audit and feedback approach will be repeated each month after the implementation of the model of care during the regular emergency staff meetings until the end of the follow-up period.

# BMJ Open

## Implementation of an evidence-based model of care for low back pain in emergency departments: Protocol for the Sydney Health Partners Emergency Department (SHaPED) trial

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SCHOLARONE™  
Manuscripts



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3 **1 Implementation of an evidence-based model of care for low back pain in emergency**  
4 **2 departments: Protocol for the Sydney Health Partners Emergency Department**  
5 **3 (SHaPED) trial**  
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\*Investigators in the SHaPED trial are listed in Supplementary Appendix 1.

1  
2  
3 27 **ABSTRACT**

4 28 **Introduction:** Patients with low back pain often seek care in emergency departments, but the  
5  
6 29 problem is that many patients receive unnecessary or ineffective interventions, and at the  
7  
8 30 same time miss out on the basics of care, such as advice on self-management. This pattern of  
9  
10 31 care has important consequences for the healthcare system (expensive and inefficient) and for  
11  
12 32 patients (poor health outcomes). We hypothesised that the implementation of an evidence-  
13  
14 33 based model of care for low back pain will improve emergency care by reducing  
15  
16 34 inappropriate overuse of tests and treatments and improving patient outcomes.

17 35 **Methods and analysis:** A stepped wedge cluster randomised controlled trial will be  
18  
19 36 conducted to implement and evaluate the use of the Agency for Clinical Innovation (ACI)  
20  
21 37 model of care for acute low back pain at four emergency departments in New South Wales,  
22  
23 38 Australia. Clinician participants will be emergency physicians, nurses and physiotherapists.  
24  
25 39 Codes from the Systematised Nomenclature of Medicine – Clinical Terms – Australian  
26  
27 40 version will be used to identify low back pain presentations. The implementation  
28  
29 41 intervention, targeting emergency clinicians, will comprise educational materials and  
30  
31 42 seminars, and an audit and feedback approach. Health service delivery outcomes are routinely  
32  
33 43 collected measures of imaging (primary outcome), opioid use, and inpatient admission. A  
34  
35 44 random sub-sample of 200 patient participants from each trial period will be included to  
36  
37 45 measure patient-reported outcomes (pain intensity, physical function, quality of life, and  
38  
39 46 experience with emergency service). The effectiveness of the implementation intervention  
40  
41 47 will be assessed by comparing the post-intervention period with the retrospective baseline  
42  
43 48 control period.

44 49 **Ethics and dissemination:** The study received ethical approval from the Sydney Local  
45  
46 50 Health District (RPAH zone) Ethics Committee (X17-0043). The results of this study will be  
47  
48 51 published in peer-reviewed journals and presented at international conferences.

49 52 **Trial registration number:** Australia New Zealand Clinical Trials Registry: ACTRN  
50  
51 53 12617001160325.

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2  
3 54 **Strengths and limitations of the study**

- 4 55 • This is a novel implementation trial looking at reducing inappropriate overuse of tests  
5 and treatments for low back pain in emergency departments  
6 56  
7  
8 57 • The stepped wedge design is particularly suited to interventions aiming to improve  
9 healthcare systems as all sites receive the intervention  
10 58  
11 59 • In this study design, intervention effects are estimated from within-emergency  
12 department differences while controlling for time trends  
13 60  
14 61 • The use of routinely collected measures reduces the burden of data collection of  
15 health service delivery outcomes in the emergency departments  
16 62  
17 63 • The inclusion of patient-reported measures will allow the understanding of the effects  
18 of the implementation on patient outcomes  
19 64  
20 65 • Incorporation of only four clusters (emergency departments) in the trial may limit the  
21 generalisability of results to other health districts  
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## 67 INTRODUCTION

### 68 Background and rationale

69 Low back pain is a common presenting complaint in emergency settings. In 2015-16 alone,  
70 there were 104,072 low back pain presentations to emergency departments in Australia,  
71 placing this condition among the top 10 reasons for emergency visits.<sup>1</sup> This condition is also  
72 a common reason for emergency department presentations across the globe, accounting for  
73 4.4% of all presentations.<sup>2</sup> Unfortunately, many patients receive low-value care for their low  
74 back pain in the emergency department. Low-value care is broadly defined as the use of an  
75 intervention that provides patients with little-to-no benefits, or cause harm.<sup>3</sup> Examples of  
76 low-value care of low back pain in emergency departments include inappropriate overuse of  
77 imaging, liberal use of opioid analgesics, and unnecessary admission to hospital.

78  
79 Multiple clinical guidelines exist for the management of low back pain in primary care.<sup>4,5</sup>  
80 Although it is unclear whether these guidelines should be applied in the emergency  
81 department, much of their recommendations may be relevant to emergency physicians and  
82 are often used to guide their practice.<sup>6</sup> However, the mixture of providing inappropriate care  
83 and failing to provide appropriate care in the emergency department is a clear indication that  
84 healthcare is not following clinical guidelines. For instance, about 30% of patients with non-  
85 specific low back pain receive imaging in the emergency department,<sup>7</sup> when guidelines  
86 explicitly recommend no imaging for these cases. Imaging in the absence of suspected  
87 serious pathology does not seem to improve patient outcomes,<sup>8</sup> and can potentially cause  
88 harms.<sup>9-11</sup> Against guideline advice, around 62% of low back pain patients receive opioids in  
89 the emergency department,<sup>12</sup> although efficacy in pain relief has not been established for  
90 acute low back pain<sup>13</sup> and side effects are often serious,<sup>14</sup> including dependence, overdose  
91 and death. Another issue is the increasing rate of hospital admissions. More than one third of  
92 low back pain presentations to the emergency department lead to the patient being admitted  
93 to hospital,<sup>7</sup> where care is likely to be similar to what could be provided in primary care.

94  
95 The significant deviations from evidence-based recommendations occurring in Australian  
96 emergency departments<sup>15</sup> makes them an appropriate setting to trial an intervention based on  
97 improving care for low back pain. The Agency for Clinical Innovation (ACI) has recently  
98 launched a model of care for acute low back pain that could be applied in both primary care  
99 and emergency department settings.<sup>16</sup> The ACI model of care was developed in collaboration  
100 with policy makers, clinicians, consumers and researchers, and distils the high quality

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2  
3 101 evidence in this area to formulate key messages for practice (Table 1). Briefly, the model  
4 102 provides different care pathways according to a classification based on a diagnostic triage<sup>17</sup>  
5  
6 103 (acute or chronic non-specific low back pain, low back pain with leg pain, and suspected  
7  
8 104 serious spinal conditions). Risk stratification<sup>18</sup> is recommended to guide the amount and type  
9  
10 105 of treatment provided; including personalised evidence-based health education and treatment.  
11 106 Lastly, follow-up reviews are scheduled to monitor individuals' progress. Passive  
12  
13 107 dissemination of guidelines, such as the ACI model of care, is unlikely to change practice.  
14 108 We are proposing a multi-faceted strategy to implement and evaluate the ACI model of care  
15  
16 109 to see if this improves health service delivery and patient-reported outcomes for low back  
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18 110 pain at the emergency department.

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## 20 112 **Objectives**

21  
22 113 The overall aim of the Sydney Health Partners Emergency Department (SHaPED) trial is to  
23  
24 114 implement and evaluate the ACI model of care for acute low back pain. The outcomes of the  
25  
26 115 trial reflect the key messages in the model: 1) patients with non-specific low back pain do not  
27  
28 116 require imaging; 2) where medicines are used, simple analgesics should be the first option; 3)  
29  
30 117 patients with non-specific low back pain should be managed as outpatients.

31 118

### 32 119 *Primary objective*

33  
34 120 The primary objective of this study is to evaluate if implementation of the ACI model of care  
35  
36 121 significantly reduces the proportion of patients presenting with low back pain who receive  
37  
38 122 imaging in the emergency department.

39 123

### 40 124 *Secondary objectives*

41  
42 125 The secondary aims of the study are:

- 43 126 • To determine if implementation of the ACI model of care significantly reduces the  
44  
45 127 proportion of patients presenting with low back pain who receive opioids in the emergency  
46  
47 128 department, and the proportion of patients subsequently admitted to hospital.
- 48 129 • To determine if implementation of the ACI model of care significantly improves patient-  
49  
50 130 reported outcomes in people who present with low back pain in the emergency  
51  
52 131 department.

- 1  
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3 132 • To determine the cost-effectiveness of the ACI model of care compared with current  
4 133 emergency department practice for people who present with low back pain.  
5  
6 134 • To determine the barriers and facilitators to the implementation intervention of the ACI  
7 135 model of care for people who present with low back pain in the emergency department.  
8  
9 136

## 11 137 **METHODS AND ANALYSIS**

### 12 138 **Study design**

13 139 The SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials)  
14 140 guidelines were followed in this report of the protocol.<sup>19</sup> SHaPED will use a stepped wedge  
15 141 cluster randomised controlled trial design.<sup>20</sup> In this study design, clusters are randomised to  
16 142 cross from the control period (i.e., unexposed to intervention) to the intervention period at  
17 143 regular intervals ('steps') until all clusters have crossed to the intervention under evaluation.  
18 144 This design is particularly suited to interventions aiming to improve healthcare systems as all  
19 145 groups eventually receive the intervention. Moreover, the process allows for comparison with  
20 146 control sites that have not yet implemented the intervention.  
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23 147  
24 148 In the SHaPED trial, after a retrospective baseline observation control period of 12 months  
25 149 prior to randomisation, the implementation intervention will be sequentially rolled out, with a  
26 150 new emergency department receiving the implementation intervention every four weeks, until  
27 151 all participating emergency departments have received the implementation intervention. After  
28 152 the implementation of the ACI model of care, the emergency departments will continue using  
29 153 the pathways of care outlined in the model until the end of the trial (Table 2).  
30  
31

### 32 154 33 155 **Study setting**

34 156 The emergency departments of one rural and three urban hospitals in New South Wales,  
35 157 Australia will participate in the study: Royal Prince Alfred Hospital, Concord Repatriation  
36 158 General Hospital, Canterbury Hospital, and Dubbo Base Hospital. The SHaPED trial has  
37 159 been approved (X17-0043) by the Ethics Review Committee of the Sydney Local Health  
38 160 District (RPAH zone), and by the Chief Executive of each participating institution. The trial  
39 161 is registered with the Australia New Zealand Clinical Trials registry: ACTRN  
40 162 12617001160325.  
41  
42

### 43 163 44 164 **Clinician participants**

1  
2  
3 165 Clinician participants included in the SHaPED trial will be emergency clinical staff, such as  
4 166 physicians, nurses, and physiotherapists, who routinely manage patients presenting to  
5 167 emergency departments with a primary complaint of low back pain. Potential clinician  
6 168 participants will be invited by the Principal Investigator of each emergency department and  
7 169 will receive a Participant Information Statement. Research staff will verbally explain the  
8 170 information provided in this document to fully inform potential clinician participants of the  
9 171 risks and benefits of their participation. In addition, the research staff will be available to  
10 172 answer any questions to ensure that potential clinician participants fully understand the  
11 173 implications of their decision. A written Participant Consent Form will be obtained from all  
12 174 participating clinicians prior to randomisation.  
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### 21 176 **Patient participants**

22 177 We will use codes from the Systematised Nomenclature of Medicine – Clinical Terms –  
23 178 Australian version, Emergency Department Reference Set (SNOMED CT-AU [EDRS])<sup>21</sup> to  
24 179 identify low back pain presentations (Supplementary Appendix 2) to the emergency  
25 180 departments. Presentations with codes related to low back pain with non-specific cause or  
26 181 those associated with neurological signs and symptoms (such as sciatica and lumbar spinal  
27 182 stenosis) will be included. Re-presentations to the emergency department, or low back pain  
28 183 presentations related to serious spinal pathologies (such as lumbar fracture or cauda equina  
29 184 syndrome) will be excluded. A random sub-sample of 200 patient participants from each trial  
30 185 period will be referred to a brief self-reported online questionnaire to evaluate the  
31 186 effectiveness of the implementation of the ACI model of care on patient-reported outcomes.  
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### 40 188 **Randomisation**

41 189 Before the beginning of the implementation intervention, the four hospitals will be randomly  
42 190 allocated the ‘step’ when the intervention will commence at their emergency department.  
43 191 Randomisation will be conducted using computer-generated random numbers by research  
44 192 staff. Only the research team will be aware of cluster allocation.  
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### 50 194 **Implementation intervention**

51 195 A framework has been proposed to facilitate the implementation of research evidence into  
52 196 clinical practice, known as The Knowledge-to-Action Process.<sup>22</sup> This framework links the  
53 197 various types of research enquiry with the key steps in the research translation cycle. The  
54 198 process consists of the knowledge creation cycle and the action cycle, and involves end users  
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3 199 of research (e.g., policymakers, clinicians and patients) to facilitate engagement with the  
4 200 implementation strategy. We will use this framework to develop a tailored intervention  
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6 201 strategy to implement the ACI model of care at the participating emergency departments.  
7  
8 202

9 203 Implementation will begin with visits to each participating emergency department to establish  
10 204 collaborations and approvals. We will also assess organisational issues and potential barriers  
11 205 to the implementation intervention, such as intake and flow of patients with low back pain,  
12 206 assessment of current practices, acceptability of new model, and specific roles of emergency  
13 207 clinicians in managing these patients. We will identify existing models of care that are used  
14 208 to guide management of patients presenting with low back pain at each emergency  
15 209 department. Then, we will work with local clinical staff to ensure that each site practices  
16 210 according to the full ACI model of care.  
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24 212 A multi-faceted intervention package will be used to implement the ACI model of care at the  
25 213 emergency departments. Briefly, the initial 4-week implementation intervention will consist  
26 214 of printed and electronic educational materials, educational seminars and educational  
27 215 outreach, website support, posters, and an audit and feedback approach. Clinician participants  
28 216 will receive a copy of the model and other printed materials, including the ACI consumer  
29 217 information booklet, as well as access to additional online support tools outlined in the ACI  
30 218 model of care, such as webpages and videos, to help them educate their patients. Experienced  
31 219 clinicians, research staff, and local opinion leaders (i.e., Directors of Emergency Medicine)  
32 220 will deliver the interactive educational seminars and educational outreach. An audit and  
33 221 feedback approach focussed on the outcomes of the study will also be used to enhance our  
34 222 implementation program. A detailed description of the implementation plan for the SHaPED  
35 223 trial can be found in Supplementary Appendix 3.  
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44 224  
45 225 The implementation intervention will be tailored for each site by adapting knowledge  
46 226 resources (such as printed decision aids and patient resources) to the local context and by  
47 227 working with local opinion leaders to address potential barriers to implementing the ACI  
48 228 model of care. These instructions, measures, and training materials will be hosted online  
49 229 during the implementation phase on The University of Sydney's website. Due to the nature of  
50 230 the intervention, it will not be possible to blind clinician participants to the intervention.  
51  
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55 231

56 232 **Sample size**



233 Based on the effect size of 10% absolute reduction (from 30%<sup>7</sup> to 20%) in imaging referrals,  
234 combined with an alpha of 0.05 and assuming an Intraclass Correlation Coefficient (ICC) of  
235 0.1, a total number of 1,920 low back pain presentations (on average 480 per cluster) to  
236 emergency departments is needed for this stepped-wedge cluster trial with 80% power. A  
237 preliminary analysis revealed that there were over 2,650 low back pain presentations to the  
238 participating emergency departments in 2016, showing feasibility of this trial.

## 240 Outcome Measures

241 Clinician participants will complete a baseline questionnaire, including demographic  
242 questions. They will also be asked to indicate whether they have special interests in low back  
243 pain or musculoskeletal medicine, and if they had attended previous continuing medical  
244 education or postgraduate training on low back pain management. The outcomes to evaluate  
245 the effectiveness of the ACI model of care on health service delivery are routinely collected  
246 emergency department measures.

### 248 *Primary outcome:*

- 249 • Proportion of patients receiving any imaging (yes/no)

### 251 *Secondary outcomes:*

- 252 • Proportion of patients receiving advanced imaging (CT/MRI=yes, X-ray/No imaging=no)
- 253 • Proportion of patients receiving analgesic medications (topical, oral, injection).  
254 Medications will be classified according to the Anatomical Therapeutic Chemical (ATC)  
255 classification system (Table 3). The ATC classification is recommended by the World  
256 Health Organisation and is widely used internationally in medication utilisation studies:
  - 257 ○ Paracetamol
  - 258 ○ Non-steroidal anti-inflammatory drugs (NSAIDs)
  - 259 ○ Muscle relaxants
  - 260 ○ Opioids
  - 261 ○ Neuropathic pain medications
  - 262 ○ Other
- 263 • Proportion of patients admitted to:
  - 264 ○ Hospital
  - 265 ○ Emergency Medical Unit (EMU)

- 266 ○ Short Stay Unit (SSU)
- 267 ● Time in emergency department (triage time to discharge or admission time)
- 268 ● Proportion of patients referred to specialists (referral for a consultation by the emergency  
269 department):
  - 270 ○ Pain Management
  - 271 ○ Rheumatology
  - 272 ○ Surgery
- 273 ● Proportion of patients re-presenting to the emergency department within 48 hours
- 274 ● Proportion of patients re-admitted to the hospital within 28 days
- 275 ● Total health system costs (including intervention costs and health service delivery costs)

276

277 Patient-reported outcomes will be collected using a brief online questionnaire that will  
278 measure pain intensity (Numeric Rating Scale, range 0–10). We will also use the Patient-  
279 Reported Outcomes Measurement Information System (PROMIS) to measure physical  
280 function (PROMIS Short Form – Physical Function 4a) and quality of life (PROMIS Scale –  
281 Global Health item 1) as advocated by the National Institutes of Health. We have chosen  
282 these outcomes as they are considered the three core outcome domains for clinical trials in  
283 low back pain identified in a recent Delphi study,<sup>23</sup> and by the International Consortium for  
284 Health Outcomes Measurement (ICHOM).<sup>24</sup> Patient experience with emergency service will  
285 be assessed using item 31 of the Emergency Department Patient Experience of Care  
286 (EDPEC) survey advocated by the American College of Emergency Medicine.<sup>25</sup>

287

### 288 **Data collection methods**

289 In the week prior to the implementation intervention, the 12-month retrospective baseline  
290 health service delivery data will be extracted directly from participating hospitals' electronic  
291 record systems. The Sydney Local Health District (SLHD) Targeted Activity and Reporting  
292 System (STARS) will be used to access and extract data from SLHD emergency departments.  
293 STARS is data analytics program which monitors clinician performance and service  
294 utilisation. At Dubbo Base Hospital, health service delivery data will be extracted from its  
295 electronic record system. During the implementation intervention, health service delivery  
296 measures will be extracted from all participating emergency departments every week until the  
297 end of the 3-month follow-up period. Data extraction will be conducted remotely for all  
298 participating emergency departments by research staff blinded to intervention allocation.

299 Data collection through hospitals' electronic systems will also avoid additional workloads  
300 within the emergency departments.

301

302 Patient-reported outcome measures will be collected using automated text messaging at one  
303 week (primary time point) and again at two and four weeks after index emergency  
304 department presentation. A random sub-sample of patient participants will be referred to a  
305 brief self-reported online questionnaire containing the Patient Information Statement.

306 Completion of the online questionnaire indicates patient consent to participate in the study.

307 Reminder messages will be used to ensure a high response rate.

308

309 Data will be securely stored in password-protected spreadsheets and transferred to  
310 appropriate statistical software for analysis. Spreadsheets will be regularly scrutinised for  
311 omissions and errors. Data will be archived at the Sydney School of Public Health, The  
312 University of Sydney for 15 years, after which data will be destroyed.

313

#### 314 **Statistical methods**

315 Data analysis will be performed according to an intention-to-treat analysis, i.e. clusters will  
316 be analysed according to their randomised crossover time irrespective of whether crossover  
317 was achieved at the desired time. Firstly, we will investigate temporal trends in healthcare  
318 outcomes across the 12-month baseline observation period. In the situation of an underlying  
319 temporal trend, we will only include data for the previous three months as the baseline  
320 observation period. In our primary analysis, the 4-week implementation intervention period  
321 will be excluded, but a secondary exploratory analysis will be performed including the  
322 implementation period into the intervention group. For the primary outcome analysis, logistic  
323 regression models with a random effect for cluster, a fixed effect indicating the group  
324 assignment of each cluster at each step, and a fixed effect of time (each step) will be used.  
325 Data will be analysed using SAS version 9.1.3 (SAS Institute Inc., Cary, NC).

326

#### 327 **Economic evaluation**

328 An economic evaluation of the ACI model of care compared with current emergency practice  
329 will be undertaken from the health system perspective. Firstly, we will measure the costs  
330 related to the delivery of the implementation intervention (that is, training component, staff  
331 time, and printed resources). Then, the costs related to health service delivery will be  
332 measured via data captured by the hospitals' electronic record systems. Costs will be valued

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3 333 based on government charges, using publicly available data. All costs will be reported in  
4 334 Australian dollars. Where necessary, costs will be converted to 2017 prices using the health  
5  
6 335 consumer price index published by the Australian Bureau of Statistics. The incremental cost-  
7  
8 336 effectiveness ratio (ICER) will be presented as the incremental cost per patient avoiding any  
9  
10 337 imaging, opioid prescription, and hospital admission.

11 338

12 339 Univariate sensitivity analyses will be conducted around key parameters likely to influence  
13  
14 340 cost-effectiveness, including cost and efficacy estimates. For example, effectiveness  
15  
16 341 parameters used in the economic evaluation will be varied over the 95% confidence intervals  
17  
18 342 to assess impact on the ICER. Intervention costs, including training costs, staff time and  
19  
20 343 resource costs will be collected from individual emergency departments and similarly  
21  
22 344 analysis will examine the effect on the ICER of varying these values over the range reported  
23  
24 345 by participating sites. Bootstrapping will be used to estimate a distribution around costs and  
25  
26 346 health outcomes, and to estimate the confidence intervals around the ICER. Results will be  
27  
28 347 plotted on the cost-effectiveness plane.

29 348

### 30 349 **Process evaluation**

31 350 A process evaluation will be conducted to provide an indication of which elements of the  
32  
33 351 implementation intervention are effective and worthwhile. In the week before the  
34  
35 352 implementation period and in the week after it, clinician participants will be asked to answer  
36  
37 353 a questionnaire containing the Back Beliefs Questionnaire.<sup>26</sup> The Back Beliefs Questionnaire  
38  
39 354 is a widely validated questionnaire<sup>27</sup> designed to measure beliefs about low back pain and  
40  
41 355 will be used in our trial to assess whether the use of the ACI model of care improves beliefs  
42  
43 356 about low back pain among emergency clinicians. This instrument was found to be reliable  
44  
45 357 and responsive to change in a wide range of contexts, including in Australia.<sup>28</sup> We will also  
46  
47 358 use a set of questions aimed at eliciting knowledge about the management of low back pain  
48  
49 359 and attitudes of emergency clinicians toward these patients.<sup>29</sup> At the end of the  
50  
51 360 implementation period, clinician participants will also be asked to review the content of  
52  
53 361 educational materials. Potential barriers and facilitators will be investigated using qualitative  
54  
55 362 interviews with clinician participants.

56 363

### 57 364 **ETHICS AND DISSEMINATION**

58 365 The SHaPED trial received ethical approval from the Sydney Local Health District (RPAH  
59  
60 366 zone) Ethics Committee, Sydney, Australia (X17-0043). Our hypothesis is that

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2  
3 367 implementation of the ACI model of care will improve health service delivery in participating  
4 368 emergency departments for patients presenting with low back pain: specifically decreasing  
5 369 the proportion of patients receiving imaging, opioids, and hospital admission. If the trial  
6 370 results are positive we will build upon our existing strong relationships with the ACI, Sydney  
7  
8 371 Health Partners, and the Local Health Districts to support implementation of the ACI model  
9 372 of care in other emergency departments across New South Wales. As a branch of the New  
10 373 South Wales Ministry of Health, the ACI will be well positioned to facilitate transferability of  
11 374 findings. We will also disseminate the results of the trial at conferences and in scientific  
12 375 journals and we will continue our successful approach of using the media to reach a lay  
13 376 audience and health consumers. The study resources will be made freely available on relevant  
14 377 websites so that jurisdictions beyond New South Wales can adopt the implementation  
15 378 strategy outlined in this study.  
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3 379 **ACKNOWLEDGMENTS**

4 380 **Contributors:** GCM, BR, CN, RB, IH, KH, KM, LB, and CM conceptualised the research  
5  
6 381 design, drafted the research protocol, and are coordinating the project team. JE, ER, RF, DLC  
7  
8 382 provided expert advice and are lead site investigators. MO, NB, HS, and RK are responsible  
9  
10 383 for the acquisition of data and data monitoring. MV, NM, KM, RD, RL, MJ, RS, NA, NM,  
11 384 MF, PF, and CL are collaborators and contributed with expert advice and funding  
12 385 applications. LB advised on the trial design and was responsible for the sample size  
13 386 calculation and statistical analysis methods. KH was responsible for the design of the  
14 387 economic evaluation. KM was responsible for the design of the process evaluation. MO, DC,  
15 388 RP, MC, MM, DH, LB, and KH are site investigators contributing to the implementation of  
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17 390 the final manuscript.

18  
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25 397 design; collection, management, analysis, and interpretation of data; writing of the report; or  
26 398 the decision to submit the report for publication.

27 399 **Patient consent:** Consent of the clinician and patient participants will be obtained.

28 400 **Ethics approval:** The study received ethical approval from the Sydney Local Health District  
29 401 (RPAH zone) Ethics Committee, Sydney, Australia (X17-0043).

30 402 **Provenance and peer review:** Not commissioned; externally peer reviewed.

31 403 **Open Access:** This is an Open Access article distributed in accordance with the Creative  
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34 406 works on different terms, provided the original work is properly cited and the use is non-  
35 407 commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

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**Table 1.** The key principles of the ACI model of care for acute low back pain

Principle 1	Assessment: history and examination
Principle 2	Risk stratification
Principle 3	Patient education
Principle 4	Active physical therapy encouraged
Principle 5	Begin with simple analgesic medicines
Principle 6	Judicious use of complex medicines
Principle 7	Cognitive behavioural approach
Principle 8	Only image those with suspected serious spinal pathology
Principle 9	Pre-determined times for review
Principle 10	Timely referral and access to specialist services

Source: NSW Agency for Clinical Innovation. Management of people with acute low back pain: model of care. Chatswood; NSW Health; 2016. 39 p, available at: <https://www.aci.health.nsw.gov.au/resources/musculoskeletal/management-of-people-with-acute-low-back-pain/albp-model>

**Table 2.** SHaPED trial design

Steps (clusters)	Year 1												Year 2						
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7
ED 1																			
ED 2																			
ED 3																			
ED 4																			

-  12-month retrospective baseline control period
-  4-week initial implementation intervention period
-  Sites continue with intervention plus follow-up period

For peer review only

**Table 3.** Medications per ATC classification

<b>Group</b>	<b>ATC code</b>
Analgesics	N02B
NSAIDs	M01A M02AA
Muscle relaxants	M03
Opioids	N02A N01AH
Neuropathic pain medicines	N03 N06A

ATC, Anatomical Therapeutic Chemical. NSAIDs, Non-steroidal anti-inflammatory drugs

For peer review only

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3 **Supplementary Appendix 1. The SHaPED trial investigators**  
4  
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6  
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**Supplementary Appendix 2.** SNOMED CT-AU (EDRS) codes related to low back pain

presentations

DESCRIPTION	CODES
<b>Low back pain with non-specific cause</b>	
Acute low back pain (finding)	278862001
Back pain complicating pregnancy (disorder)	91957002
Backache (finding)	161891005
Blunt injury to back (disorder)	424270008
Chronic back pain (finding)	134407002
Chronic low back pain (finding)	278860009
Coccyx sprain (disorder)	209571002
Complaining of low back pain (finding)	161894002
Degeneration of lumbar intervertebral disc (disorder)	26538006
Displacement of lumbar intervertebral disc without myelopathy (disorder)	20021007
Exacerbation of backache (finding)	135860001
Low back pain (finding)	279039007
Low back strain (disorder)	300956001
Lower back injury (disorder)	282766005
Lumbar spondylosis (disorder)	239880009
Lumbar sprain (disorder)	209565008
Mechanical low back pain (finding)	279040009
Pain in the coccyx (finding)	34789001
Sacral back pain (finding)	61486003
Spasm of back muscles (finding)	203095000
Sprain of ligament of lumbosacral joint (disorder)	209548004
Stiff back (finding)	249921008
Strain of back muscle (disorder)	262965006
Strain of tendon of back (disorder)	262975009
<b>Low back pain with neurological signs and symptoms</b>	
Acute back pain with sciatica (finding)	247366003
Acute sciatica (disorder)	307176005
Chronic sciatica (disorder)	307177001
Injury of lumbar nerve roots (disorder)	24300005
Injury of sciatic nerve (disorder)	86269002
Lumbago with sciatica (finding)	202794004
Lumbago-sciatica due to displacement of lumbar intervertebral disc (disorder)	46960006
Lumbar disc prolapse with radiculopathy (disorder)	202735001
Lumbar radiculopathy (disorder)	128196005
Sciatica (disorder)	23056005
Spinal stenosis of lumbar region (disorder)	18347007
<b>Low back pain due to serious pathology</b>	
Abscess of back (disorder)	309083007
Abscess of back, except buttock (disorder)	19284003
Cauda equina syndrome (disorder)	192970008
Closed fracture lumbar vertebra (disorder)	207957008
Collapse of lumbar vertebra (disorder)	308758008
Compression fracture of lumbar spine (disorder)	426646004
Concussion and edema of lumbar spinal cord (disorder)	212360005
Contusion of back (disorder)	11437003
Contusion of lower back (disorder)	284062002
Crush fracture of lumbar vertebra (disorder)	281933002
Disc prolapse with myelopathy (disorder)	202728009

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2		
3	Discitis (disorder)	2304001
4	Fracture of coccyx (disorder)	125871005
5	Fracture of lumbar spine (disorder)	125608002
6	Fracture of lumbar spine and/or pelvis (disorder)	207986006
7	Injury of cauda equina (disorder)	230614002
8	Lumbar disc prolapse with myelopathy (disorder)	202731005
9	Multiple fractures of lumbar spine and/or pelvis (disorder)	207993005
10	Open dislocation of coccyx (disorder)	44237008
11	Open fracture of lumbar vertebra with spinal cord injury (disorder)	48956000
12	Open fracture of sacrum AND/OR coccyx with spinal cord injury (disorder)	65491009
13	Traumatic dislocation of joint of lumbar vertebra (disorder)	129166009
14	Traumatic dislocation of lumbosacral joint (disorder)	129161004
15		
16	SNOMED CT-AU (EDRS), Systematized Nomenclature of Medicine – Clinical Terms – Australian	
17	Version (Emergency Department Reference Set).	
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### Supplementary Appendix 3. SHaPED Implementation strategy and intervention description

The implementation plan for the Sydney Health Partners Emergency Department (SHaPED) trial has been adapted from: Jabbour M, Reid S, Polihronis C, Cloutier P, Gardner W, Kennedy A, Gray C, Zemek R, Pajer K, Barrowman N, Cappelli M. Improving mental health care transitions for children and youth: a protocol to implement and evaluate an emergency department clinical pathway. *Implement Sci.* 2016;11:90.

#### 1. Create implementation team:

- a) Obtain support from clinical leads and administration heads at the four emergency departments. Formalise a partnership agreement between institutions.
- b) Recruit and engage study champions at each emergency department. Team members to include: emergency physicians, physiotherapists, nurses, managers, and clinical educators.
- c) Develop a working group and form a steering committee at each emergency department to provide oversight on implementation progress.
- d) Establish meeting schedule: local steering committee to meet twice a week and report to study supervisors every week during the implementation period.

#### 2. Assessment:

- a) Review and discuss the existing models of care for low back pain at the four emergency departments and recommend adaptation to facilitate adoption of the new model.
- b) Conduct an environmental assessment and identify typical pathway of care for a patient presenting with low back pain at each emergency department.
- c) Identify practices and processes that require development or change in order to support the implementation strategy.
- d) Identify internal and external stakeholders who will be impacted by the new model and therefore require education and support to implement it.

#### 3. Plan strategy for change

- a) Identify leadership support required for implementation phase.
- b) Identify and engage influential clinical champions who will effectively drive change.
- c) Revise or develop policies as needed.
- d) Develop a knowledge translation strategy to support practice change, such as shared staff meetings, educational rounds, peer-to-peer mentoring.

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3 e) Identify factors that will support practice change, such as engaging all potential  
4 stakeholders, scheduling champions and clinicians to enable attendance at meetings and  
5 face-to-face education sessions, facilitating the development of relationships between  
6 emergency physicians and other clinical staff, conducting audits or monitor specific data  
7 indicators that will support practice change.  
8  
9  
10  
11 f) Identify factors that may create a barrier for practice change in the emergency department,  
12 including attitudes and beliefs about low back pain management, and lack of clinician  
13 expertise/comfort to treat this population.  
14  
15 g) Develop strategies to manage barriers, such as communication, education, opportunities to  
16 develop relationships within and between clinicians and service provider.  
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21

#### 22 **4. Implementation:**

- 23 a) Provide clinician information package:  
24  
25
  - 26 • Deliver printed copies of the ACI Model of care (full version and executive summary) to  
27 clinician participants.
  - 28 • Create a list of “red flags” to screen for serious pathologies from the ACI Model of care  
29 and deliver a printed version to clinician participants.
  - 30 • Create posters outlining the ‘10 principles’ of the ACI model of care, as well as the  
31 clinical pathways and place them at key locations of each participating emergency  
32 department.
  - 33 • Inform clinician participants about and provide them access to online videos and other  
34 printed (such as the ACI consumer information booklet) and electronic educational  
35 materials to educate patients with low back pain at emergency discharge.  
36  
37

38 b) Provide patient information package:  
39  
40
  - 41 • Encourage clinician participants to provide a printed copy of the ACI consumer  
42 information booklet to patients with low back pain during emergency department visit.
  - 43 • Where most of the patient population do not speak English, encourage clinician  
44 participants to provide a copy of the Emergency Care Institute (ECI) Patient Factsheet for  
45 low back pain (available in six languages).
  - 46 • Create posters outlining four myths of low back pain management and placed them at the  
47 reception area of each emergency department.  
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3 c) Deliver clinician education:  
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- 5 • Educational seminars will be delivered by an experienced clinician (Dr Chris Needs) at  
6 week 1 of the intervention period. Booster sessions in the first week will also be conducted  
7 by local investigators (such as Directors of Emergency Medicine, clinical educators) as  
8 required, as well as in weeks 2 to 4.  
9  
10 • The educational seminars will be conducted primarily during the existing regular clinical  
11 staff meetings, but additional sessions will be scheduled to reach all emergency clinicians.  
12 The format of the seminars consists of a mini-lecture and interactive group discussions  
13 and will last for 40 to 60 minutes.  
14  
15 • During the educational seminars, clinician participants will be trained on history taking  
16 and examination of patients with low back pain, on how to use SNOMED diagnosis codes,  
17 and will be encouraged to follow the recommendations in the ACI model of care to  
18 manage these patients, with focus on the key outcomes of this study (that is, imaging,  
19 opioids, and inpatient admission rates).  
20  
21 • During weeks 1 to 4, individual meetings with clinician participants will be scheduled as  
22 required to cover the key messages and principles outlined in the ACI model of care.  
23 There will be at least one educational outreach visit to each clinician in weeks 1 to 4 and  
24 they can request additional if they have any concerns. Clinician participants can also seek  
25 advice from clinical educators by email.  
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38 d) Develop audit and feedback focussed on study outcomes  
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- 40 • Each emergency department and clinician participant will receive at the first  
41 educational seminar session an emergency department level feedback on the 12-  
42 month retrospective data performance against the outcomes of this study (that is,  
43 imaging, opioids, inpatient admission rates).  
44  
45 • This audit and feedback approach will be repeated each month after the  
46 implementation of the model of care during the regular emergency staff meetings  
47 until the end of the follow-up period.  
48  
49 • Clinician participants at the Sydney Local Health District (SLHD) will be encouraged  
50 to use the SLHD Targeted Activity and Reporting System (STARS) to monitor the  
51 emergency department performance during and after the implementation period.  
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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents\*

Section/item	Item No	Description	Addressed on page number
<b>Administrative information</b>			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2, 6_____
	2b	All items from the World Health Organization Trial Registration Data Set	N/A_____
Protocol version	3	Date and version identifier	Footer_____
Funding	4	Sources and types of financial, material, and other support	14_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	14, Appendix 1_
	5b	Name and contact information for the trial sponsor	14_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	14_____
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Appendix 1_____

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**Introduction**

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4, 5_____
	6b	Explanation for choice of comparators	N/A_____
Objectives	7	Specific objectives or hypotheses	5, 6_____
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6_____

**Methods: Participants, interventions, and outcomes**

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6, 7_____
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7, 8_____
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	7, 8, 12_____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A_____
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9, 10_____
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Table 2_____

1				
2				
3	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	8, 9_____
4				
5	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	10, 11_____
6				
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### 8 **Methods: Assignment of interventions (for controlled trials)**

#### 9 Allocation:

10				
11				
12	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	7_____
13				
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17	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	7_____
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21	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7_____
22				
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24	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8, 10_____
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27		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A_____
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### 31 **Methods: Data collection, management, and analysis**

32				
33	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	10, 11_____
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38		18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	11_____
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Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	11_____
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	11_____
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	11, 12_____
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	N/A_____

**Methods: Monitoring**

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Appendix 1_____
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A_____
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A_____

**Ethics and dissemination**

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	12, 13_____
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	13_____



1				
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3	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7, 11, 14_____
4				
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6		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A_____
7				
8	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	In ACTRN _____
9				
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11	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	14_____
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14	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14_____
15				
16				
17	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A_____
18				
19				
20	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	In ACTRN _____
21				
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25		31b	Authorship eligibility guidelines and any intended use of professional writers	Appendix 1_____
26				
27		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A_____
28				
29	<b>Appendices</b>			
30				
31	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A_____
32				
33				
34	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A_____
35				
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37 \*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items.  
 38 Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons  
 39 "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.  
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# BMJ Open

## Implementation of an evidence-based model of care for low back pain in emergency departments: Protocol for the Sydney Health Partners Emergency Department (SHaPED) trial

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-019052.R2
Article Type:	Protocol
Date Submitted by the Author:	30-Jan-2018
Complete List of Authors:	Machado, Gustavo; University of Sydney - Camperdown and Darlington Campus, School of Public Health Richards, Bethan; Royal Prince Alfred Hospital, Rheumatology Department Needs, Chris; Royal Prince Alfred Hospital, Rheumatology Department Buchbinder, Rachelle; Monash University, Dept of Epidemiology and Preventive Medicine Harris, Ian; University of New South Wales, South Western Sydney Clinical School Howard, Kirsten; University of Sydney, School of Public Health McCaffery, Kirsten; The University of Sydney, Screening and Test Evaluation Program (STEP), School of Public Health; The University of Sydney, Centre for Medical Psychology & Evidence-based Decision-making (CeMPED) Billot, Laurent; The George Institute for Global Health, Statistics Division Edwards, James; Royal Prince Alfred Hospital, Emergency Department Rogan, Eileen; Canterbury Hospital, Emergency Department Facer, Rochelle; Concord Repatriation General Hospital, Emergency Department Lord Cowell, David; Dubbo Base Hospital, Emergency Department Maher, Chris; University of Sydney - Camperdown and Darlington Campus, School of Public Health
<b>Primary Subject Heading</b>:	Health services research
Secondary Subject Heading:	Emergency medicine
Keywords:	Low back pain, Clinical trials < THERAPEUTICS, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

SCHOLARONE™  
Manuscripts

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3 **1 Implementation of an evidence-based model of care for low back pain in emergency**  
4 **2 departments: Protocol for the Sydney Health Partners Emergency Department**  
5 **3 (SHaPED) trial**  
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10 Gustavo C Machado,<sup>1,2</sup> Bethan Richards,<sup>2,3</sup> Chris Needs,<sup>3</sup> Rachelle Buchbinder,<sup>4,5</sup> Ian  
11 Harris,<sup>6</sup> Kirsten Howard,<sup>1</sup> Kirsten McCaffery,<sup>1</sup> Laurent Billot,<sup>7</sup> James Edwards,<sup>8</sup> Eileen  
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44 \*Investigators in the SHaPED trial are listed in Supplementary Appendix 1.  
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3 27 **ABSTRACT**

4 28 **Introduction:** Patients with low back pain often seek care in emergency departments, but the  
5  
6 29 problem is that many patients receive unnecessary or ineffective interventions, and at the  
7  
8 30 same time miss out on the basics of care, such as advice on self-management. This pattern of  
9  
10 31 care has important consequences for the healthcare system (expensive and inefficient) and for  
11  
12 32 patients (poor health outcomes). We hypothesised that the implementation of an evidence-  
13  
14 33 based model of care for low back pain will improve emergency care by reducing  
15  
16 34 inappropriate overuse of tests and treatments and improving patient outcomes.

17 35 **Methods and analysis:** A stepped wedge cluster randomised controlled trial will be  
18  
19 36 conducted to implement and evaluate the use of the Agency for Clinical Innovation (ACI)  
20  
21 37 model of care for acute low back pain at four emergency departments in New South Wales,  
22  
23 38 Australia. Clinician participants will be emergency physicians, nurses and physiotherapists.  
24  
25 39 Codes from the Systematised Nomenclature of Medicine – Clinical Terms – Australian  
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27 40 version will be used to identify low back pain presentations. The implementation  
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29 41 intervention, targeting emergency clinicians, will comprise educational materials and  
30  
31 42 seminars, and an audit and feedback approach. Health service delivery outcomes are routinely  
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33 43 collected measures of imaging (primary outcome), opioid use, and inpatient admission. A  
34  
35 44 random sub-sample of 200 patient participants from each trial period will be included to  
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37 45 measure patient-reported outcomes (pain intensity, physical function, quality of life, and  
38  
39 46 experience with emergency service). The effectiveness of the implementation intervention  
40  
41 47 will be assessed by comparing the post-intervention period with the retrospective baseline  
42  
43 48 control period.

44 49 **Ethics and dissemination:** The study received ethical approval from the Sydney Local  
45  
46 50 Health District (RPAH zone) Ethics Committee (X17-0043). The results of this study will be  
47  
48 51 published in peer-reviewed journals and presented at international conferences.

49 52 **Trial registration number:** Australia New Zealand Clinical Trials Registry: ACTRN  
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51 53 12617001160325.

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3 54 **Strengths and limitations of the study**

- 4 55 • This is a novel implementation trial looking at reducing inappropriate overuse of tests  
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6 56 and treatments for low back pain in emergency departments  
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8 57 • The stepped wedge design is particularly suited to interventions aiming to improve  
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10 58 healthcare systems as all sites receive the intervention  
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12 59 • In this study design, intervention effects are estimated from within-emergency  
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14 60 department differences while controlling for time trends  
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16 61 • The use of routinely collected measures reduces the burden of data collection of  
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18 62 health service delivery outcomes in the emergency departments  
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20 63 • Incorporation of only four clusters (emergency departments) in the trial may limit the  
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22 64 generalisability of results to other health districts  
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## 65 INTRODUCTION

### 66 Background and rationale

67 Low back pain is a common presenting complaint in emergency settings. In 2015-16 alone,  
68 there were 104,072 low back pain presentations to emergency departments in Australia,  
69 placing this condition among the top 10 reasons for emergency visits.<sup>1</sup> This condition is also  
70 a common reason for emergency department presentations across the globe, accounting for  
71 4.4% of all presentations.<sup>2</sup> Unfortunately, many patients receive low-value care for their low  
72 back pain in the emergency department. Low-value care is broadly defined as the use of an  
73 intervention that provides patients with little-to-no benefits, or cause harm.<sup>3</sup> Examples of  
74 low-value care of low back pain in emergency departments include inappropriate overuse of  
75 imaging, liberal use of opioid analgesics, and unnecessary admission to hospital.

76  
77 Multiple clinical guidelines exist for the management of low back pain in primary care.<sup>4,5</sup>  
78 Although it is unclear whether these guidelines should be applied in the emergency  
79 department, much of their recommendations may be relevant to emergency physicians and  
80 are often used to guide their practice.<sup>6</sup> However, the mixture of providing inappropriate care  
81 and failing to provide appropriate care in the emergency department is a clear indication that  
82 healthcare is not following clinical guidelines. For instance, about 30% of patients with non-  
83 specific low back pain receive imaging in the emergency department,<sup>7</sup> when guidelines  
84 explicitly recommend no imaging for these cases. Imaging in the absence of suspected  
85 serious pathology does not seem to improve patient outcomes,<sup>8</sup> and can potentially cause  
86 harms.<sup>9-11</sup> Against guideline advice, around 62% of low back pain patients receive opioids in  
87 the emergency department,<sup>12</sup> although efficacy in pain relief has not been established for  
88 acute low back pain<sup>13</sup> and side effects are often serious,<sup>14</sup> including dependence, overdose  
89 and death. Another issue is the increasing rate of hospital admissions. More than one third of  
90 low back pain presentations to the emergency department lead to the patient being admitted  
91 to hospital,<sup>7</sup> where care is likely to be similar to what could be provided in primary care.

92  
93 The significant deviations from evidence-based recommendations occurring in Australian  
94 emergency departments<sup>15</sup> makes them an appropriate setting to trial an intervention based on  
95 improving care for low back pain. The Agency for Clinical Innovation (ACI) has recently  
96 launched a model of care for acute low back pain that could be applied in both primary care  
97 and emergency department settings.<sup>16</sup> The ACI model of care was developed in collaboration  
98 with policy makers, clinicians, consumers and researchers, and distils the high quality

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3 99 evidence in this area to formulate key messages for practice (Table 1). Briefly, the model  
4 100 provides different care pathways according to a classification based on a diagnostic triage<sup>17</sup>  
5  
6 101 (acute or chronic non-specific low back pain, low back pain with leg pain, and suspected  
7  
8 102 serious spinal conditions). Risk stratification<sup>18</sup> is recommended to guide the amount and type  
9  
10 103 of treatment provided; including personalised evidence-based health education and treatment.  
11 104 Lastly, follow-up reviews are scheduled to monitor individuals' progress. Passive  
12 105 dissemination of guidelines, such as the ACI model of care, is unlikely to change practice.  
13  
14 106 We are proposing a multi-faceted strategy to implement and evaluate the ACI model of care  
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16 107 to see if this improves health service delivery and patient-reported outcomes for low back  
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18 108 pain at the emergency department.  
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## 21 110 **Objectives**

22 111 The overall aim of the Sydney Health Partners Emergency Department (SHaPED) trial is to  
23 112 implement and evaluate the ACI model of care for acute low back pain. The outcomes of the  
24 113 trial reflect the key messages in the model: 1) patients with non-specific low back pain do not  
25 114 require imaging; 2) where medicines are used, simple analgesics should be the first option; 3)  
26 115 patients with non-specific low back pain should be managed as outpatients.  
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### 31 117 *Primary objective*

32 118 The primary objective of this study is to evaluate if implementation of the ACI model of care  
33 119 significantly reduces the proportion of patients presenting with low back pain who receive  
34 120 imaging in the emergency department.  
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### 39 122 *Secondary objectives*

40 123 The secondary aims of the study are:

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43 124 • To determine if implementation of the ACI model of care significantly reduces the  
44 125 proportion of patients presenting with low back pain who receive opioids in the emergency  
45 126 department, and the proportion of patients subsequently admitted to hospital.  
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47 127 • To determine if implementation of the ACI model of care significantly improves patient-  
48 128 reported outcomes in people who present with low back pain in the emergency  
49 129 department.  
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3 130 • To determine the cost-effectiveness of the ACI model of care compared with current  
4 131 emergency department practice for people who present with low back pain.  
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6 132 • To determine the barriers and facilitators to the implementation intervention of the ACI  
7 133 model of care for people who present with low back pain in the emergency department.  
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## 11 135 **METHODS AND ANALYSIS**

### 12 136 **Study design**

13 137 The SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials)  
14 138 guidelines were followed in this report of the protocol.<sup>19</sup> SHaPED will use a stepped wedge  
15 139 cluster randomised controlled trial design.<sup>20</sup> In this study design, clusters are randomised to  
16 140 cross from the control period (i.e., unexposed to intervention) to the intervention period at  
17 141 regular intervals ('steps') until all clusters have crossed to the intervention under evaluation.  
18 142 This design is particularly suited to interventions aiming to improve healthcare systems as all  
19 143 groups eventually receive the intervention. Moreover, the process allows for comparison with  
20 144 control sites that have not yet implemented the intervention.  
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29 146 In the SHaPED trial, after a retrospective baseline observation control period of 12 months  
30 147 prior to randomisation, the implementation intervention will be sequentially rolled out, with a  
31 148 new emergency department receiving the implementation intervention every four weeks, until  
32 149 all participating emergency departments have received the implementation intervention. After  
33 150 the implementation of the ACI model of care, the emergency departments will continue using  
34 151 the pathways of care outlined in the model until the end of the trial (Table 2).  
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### 40 152 41 153 **Study setting**

42 154 The emergency departments of one rural and three urban hospitals in New South Wales,  
43 155 Australia will participate in the study: Royal Prince Alfred Hospital, Concord Repatriation  
44 156 General Hospital, Canterbury Hospital, and Dubbo Base Hospital. The SHaPED trial has  
45 157 been approved (X17-0043) by the Ethics Review Committee of the Sydney Local Health  
46 158 District (RPAH zone), and by the Chief Executive of each participating institution. The trial  
47 159 is registered with the Australia New Zealand Clinical Trials registry: ACTRN  
48 160 12617001160325. Investigators in the SHaPED trial are listed in Supplementary Appendix 1.  
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### 54 161 55 162 **Clinician participants**

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3 163 Clinician participants included in the SHaPED trial will be emergency clinical staff, such as  
4 164 physicians, nurses, and physiotherapists, who routinely manage patients presenting to  
5 165 emergency departments with a primary complaint of low back pain. Potential clinician  
6 166 participants will be invited by the Principal Investigator of each emergency department and  
7 167 will receive a Participant Information Statement. Research staff will verbally explain the  
8 168 information provided in this document to fully inform potential clinician participants of the  
9 169 risks and benefits of their participation. In addition, the research staff will be available to  
10 170 answer any questions to ensure that potential clinician participants fully understand the  
11 171 implications of their decision. A written Participant Consent Form will be obtained from all  
12 172 participating clinicians prior to randomisation.  
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### 21 174 **Patient participants**

22 175 We will use codes from the Systematised Nomenclature of Medicine – Clinical Terms –  
23 176 Australian version, Emergency Department Reference Set (SNOMED CT-AU [EDRS])<sup>21</sup> to  
24 177 identify low back pain presentations (Supplementary Appendix 2) to the emergency  
25 178 departments. Presentations with codes related to low back pain with non-specific cause or  
26 179 those associated with neurological signs and symptoms (such as sciatica and lumbar spinal  
27 180 stenosis) will be included. Re-presentations to the emergency department, or low back pain  
28 181 presentations related to serious spinal pathologies (such as lumbar fracture or cauda equina  
29 182 syndrome) will be excluded. A random sub-sample of 200 patient participants from each trial  
30 183 period will be referred to a brief self-reported online questionnaire to evaluate the  
31 184 effectiveness of the implementation of the ACI model of care on patient-reported outcomes.  
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### 40 186 **Randomisation**

41 187 Before the beginning of the implementation intervention, the four hospitals will be randomly  
42 188 allocated the ‘step’ when the intervention will commence at their emergency department.  
43 189 Randomisation will be conducted using computer-generated random numbers by research  
44 190 staff. Only the research team will be aware of cluster allocation.  
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### 50 192 **Implementation intervention**

51 193 A framework has been proposed to facilitate the implementation of research evidence into  
52 194 clinical practice, known as The Knowledge-to-Action Process.<sup>22</sup> This framework links the  
53 195 various types of research enquiry with the key steps in the research translation cycle. The  
54 196 process consists of the knowledge creation cycle and the action cycle, and involves end users  
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3 197 of research (e.g., policymakers, clinicians and patients) to facilitate engagement with the  
4 198 implementation strategy. We will use this framework to develop a tailored intervention  
5  
6 199 strategy to implement the ACI model of care at the participating emergency departments.  
7  
8 200

9 201 Implementation will begin with visits to each participating emergency department to establish  
10 202 collaborations and approvals. We will also assess organisational issues and potential barriers  
11 203 to the implementation intervention, such as intake and flow of patients with low back pain,  
12 204 assessment of current practices, acceptability of new model, and specific roles of emergency  
13 205 clinicians in managing these patients. We will identify existing models of care that are used  
14 206 to guide management of patients presenting with low back pain at each emergency  
15 207 department. Then, we will work with local clinical staff to ensure that each site practices  
16 208 according to the full ACI model of care.  
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24 210 A multi-faceted intervention package will be used to implement the ACI model of care at the  
25 211 emergency departments. Briefly, the initial 4-week implementation intervention will consist  
26 212 of printed and electronic educational materials, educational seminars and educational  
27 213 outreach, website support, posters, and an audit and feedback approach. Clinician participants  
28 214 will receive a copy of the model and other printed materials, including the ACI consumer  
29 215 information booklet, as well as access to additional online support tools outlined in the ACI  
30 216 model of care, such as webpages and videos, to help them educate their patients. Experienced  
31 217 clinicians, research staff, and local opinion leaders (i.e., Directors of Emergency Medicine)  
32 218 will deliver the interactive educational seminars and educational outreach. An audit and  
33 219 feedback approach focussed on the outcomes of the study will also be used to enhance our  
34 220 implementation program. A detailed description of the implementation plan for the SHaPED  
35 221 trial can be found in Supplementary Appendix 3.  
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45 223 The implementation intervention will be tailored for each site by adapting knowledge  
46 224 resources (such as printed decision aids and patient resources) to the local context and by  
47 225 working with local opinion leaders to address potential barriers to implementing the ACI  
48 226 model of care. These instructions, measures, and training materials will be hosted online  
49 227 during the implementation phase on The University of Sydney's website. Due to the nature of  
50 228 the intervention, it will not be possible to blind clinician participants to the intervention.  
51  
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55 229  
56 230 **Sample size**



231 Based on the effect size of 10% absolute reduction (from 30%<sup>7</sup> to 20%) in imaging referrals,  
232 combined with an alpha of 0.05 and assuming an Intraclass Correlation Coefficient (ICC) of  
233 0.1, a total number of 1,920 low back pain presentations (on average 480 per cluster) to  
234 emergency departments is needed for this stepped-wedge cluster trial with 80% power. A  
235 preliminary analysis revealed that there were over 2,650 low back pain presentations to the  
236 participating emergency departments in 2016, showing feasibility of this trial.

## 238 Outcome Measures

239 Clinician participants will complete a baseline questionnaire, including demographic  
240 questions. They will also be asked to indicate whether they have special interests in low back  
241 pain or musculoskeletal medicine, and if they had attended previous continuing medical  
242 education or postgraduate training on low back pain management. The outcomes to evaluate  
243 the effectiveness of the ACI model of care on health service delivery are routinely collected  
244 emergency department measures.

### 246 *Primary outcome:*

- 247 • Proportion of patients receiving any imaging (yes/no)

### 249 *Secondary outcomes:*

- 250 • Proportion of patients receiving advanced imaging (CT/MRI=yes, X-ray/No imaging=no)
- 251 • Proportion of patients receiving analgesic medications (topical, oral, injection).  
252 Medications will be classified according to the Anatomical Therapeutic Chemical (ATC)  
253 classification system (Table 3). The ATC classification is recommended by the World  
254 Health Organisation and is widely used internationally in medication utilisation studies:
  - 255 ○ Paracetamol
  - 256 ○ Non-steroidal anti-inflammatory drugs (NSAIDs)
  - 257 ○ Muscle relaxants
  - 258 ○ Opioids
  - 259 ○ Neuropathic pain medications
  - 260 ○ Other
- 261 • Proportion of patients admitted to:
  - 262 ○ Hospital
  - 263 ○ Emergency Medical Unit (EMU)



- 264 ○ Short Stay Unit (SSU)
- 265 ● Time in emergency department (triage time to discharge or admission time)
- 266 ● Proportion of patients referred to specialists (referral for a consultation by the emergency  
267 department):
  - 268 ○ Pain Management
  - 269 ○ Rheumatology
  - 270 ○ Surgery
- 271 ● Proportion of patients re-presenting to the emergency department within 48 hours
- 272 ● Proportion of patients re-admitted to the hospital within 28 days
- 273 ● Total health system costs (including intervention costs and health service delivery costs)

274

275 Patient-reported outcomes will be collected using a brief online questionnaire that will  
276 measure pain intensity (Numeric Rating Scale, range 0–10). We will also use the Patient-  
277 Reported Outcomes Measurement Information System (PROMIS) to measure physical  
278 function (PROMIS Short Form – Physical Function 4a) and quality of life (PROMIS Scale –  
279 Global Health item 1) as advocated by the National Institutes of Health. We have chosen  
280 these outcomes as they are considered the three core outcome domains for clinical trials in  
281 low back pain identified in a recent Delphi study,<sup>23</sup> and by the International Consortium for  
282 Health Outcomes Measurement (ICHOM).<sup>24</sup> Patient experience with emergency service will  
283 be assessed using item 31 of the Emergency Department Patient Experience of Care  
284 (EDPEC) survey advocated by the American College of Emergency Medicine.<sup>25</sup>

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### 286 **Data collection methods**

287 In the week prior to the implementation intervention, the 12-month retrospective baseline  
288 health service delivery data will be extracted directly from participating hospitals' electronic  
289 record systems. The Sydney Local Health District (SLHD) Targeted Activity and Reporting  
290 System (STARS) will be used to access and extract data from SLHD emergency departments.  
291 STARS is data analytics program which monitors clinician performance and service  
292 utilisation. At Dubbo Base Hospital, health service delivery data will be extracted from its  
293 electronic record system. During the implementation intervention, health service delivery  
294 measures will be extracted from all participating emergency departments every week until the  
295 end of the 3-month follow-up period. Data extraction will be conducted remotely for all  
296 participating emergency departments by research staff blinded to intervention allocation.

297 Data collection through hospitals' electronic systems will also avoid additional workloads  
298 within the emergency departments.  
299  
300 Patient-reported outcome measures will be collected using automated text messaging at one  
301 week (primary time point) and again at two and four weeks after index emergency  
302 department presentation. A random sub-sample of patient participants will be referred to a  
303 brief self-reported online questionnaire containing the Patient Information Statement.  
304 Completion of the online questionnaire indicates patient consent to participate in the study.  
305 Reminder messages will be used to ensure a high response rate.  
306  
307 Data will be securely stored in password-protected spreadsheets and transferred to  
308 appropriate statistical software for analysis. Spreadsheets will be regularly scrutinised for  
309 omissions and errors. Data will be archived at the Sydney School of Public Health, The  
310 University of Sydney for 15 years, after which data will be destroyed.

### 312 **Statistical methods**

313 Data analysis will be performed according to an intention-to-treat analysis, i.e. clusters will  
314 be analysed according to their randomised crossover time irrespective of whether crossover  
315 was achieved at the desired time. Firstly, we will investigate temporal trends in healthcare  
316 outcomes across the 12-month baseline observation period. In the situation of an underlying  
317 temporal trend, we will only include data for the previous three months as the baseline  
318 observation period. In our primary analysis, the 4-week implementation intervention period  
319 will be excluded, but a secondary exploratory analysis will be performed including the  
320 implementation period into the intervention group. For the primary outcome analysis, logistic  
321 regression models with a random effect for cluster, a fixed effect indicating the group  
322 assignment of each cluster at each step, and a fixed effect of time (each step) will be used.  
323 Data will be analysed using SAS version 9.1.3 (SAS Institute Inc., Cary, NC).

### 325 **Economic evaluation**

326 An economic evaluation of the ACI model of care compared with current emergency practice  
327 will be undertaken from the health system perspective. Firstly, we will measure the costs  
328 related to the delivery of the implementation intervention (that is, training component, staff  
329 time, and printed resources). Then, the costs related to health service delivery will be  
330 measured via data captured by the hospitals' electronic record systems. Costs will be valued

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3 331 based on government charges, using publicly available data. All costs will be reported in  
4 332 Australian dollars. Where necessary, costs will be converted to 2017 prices using the health  
5 333 consumer price index published by the Australian Bureau of Statistics. The incremental cost-  
6 334 effectiveness ratio (ICER) will be presented as the incremental cost per patient avoiding any  
7  
8 335 imaging, opioid prescription, and hospital admission.  
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11 336

12 337 Univariate sensitivity analyses will be conducted around key parameters likely to influence  
13 338 cost-effectiveness, including cost and efficacy estimates. For example, effectiveness  
14 339 parameters used in the economic evaluation will be varied over the 95% confidence intervals  
15 340 to assess impact on the ICER. Intervention costs, including training costs, staff time and  
16 341 resource costs will be collected from individual emergency departments and similarly  
17 342 analysis will examine the effect on the ICER of varying these values over the range reported  
18 343 by participating sites. Bootstrapping will be used to estimate a distribution around costs and  
19 344 health outcomes, and to estimate the confidence intervals around the ICER. Results will be  
20 345 plotted on the cost-effectiveness plane.  
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### 28 347 **Process evaluation**

29 348 A process evaluation will be conducted to provide an indication of which elements of the  
30 349 implementation intervention are effective and worthwhile. In the week before the  
31 350 implementation period and in the week after it, clinician participants will be asked to answer  
32 351 a questionnaire containing the Back Beliefs Questionnaire.<sup>26</sup> The Back Beliefs Questionnaire  
33 352 is a widely validated questionnaire<sup>27</sup> designed to measure beliefs about low back pain and  
34 353 will be used in our trial to assess whether the use of the ACI model of care improves beliefs  
35 354 about low back pain among emergency clinicians. This instrument was found to be reliable  
36 355 and responsive to change in a wide range of contexts, including in Australia.<sup>28</sup> We will also  
37 356 use a set of questions aimed at eliciting knowledge about the management of low back pain  
38 357 and attitudes of emergency clinicians toward these patients.<sup>29</sup> At the end of the  
39 358 implementation period, clinician participants will also be asked to review the content of  
40 359 educational materials. Potential barriers and facilitators will be investigated using qualitative  
41 360 interviews with clinician participants.  
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### 52 362 **ETHICS AND DISSEMINATION**

53 363 The SHaPED trial received ethical approval from the Sydney Local Health District (RPAH  
54 364 zone) Ethics Committee, Sydney, Australia (X17-0043). Our hypothesis is that

1  
2  
3 365 implementation of the ACI model of care will improve health service delivery in participating  
4 366 emergency departments for patients presenting with low back pain: specifically decreasing  
5  
6 367 the proportion of patients receiving imaging, opioids, and hospital admission. If the trial  
7  
8 368 results are positive we will build upon our existing strong relationships with the ACI, Sydney  
9  
10 369 Health Partners, and the Local Health Districts to support implementation of the ACI model  
11  
12 370 of care in other emergency departments across New South Wales. As a branch of the New  
13  
14 371 South Wales Ministry of Health, the ACI will be well positioned to facilitate transferability of  
15  
16 372 findings. We will also disseminate the results of the trial at conferences and in scientific  
17  
18 373 journals and we will continue our successful approach of using the media to reach a lay  
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20 374 audience and health consumers. The study resources will be made freely available on relevant  
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22 375 websites so that jurisdictions beyond New South Wales can adopt the implementation  
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24 376 strategy outlined in this study.  
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3 377 **ACKNOWLEDGMENTS**

4 378 **Contributors:** GCM, BR, CN, RB, IH, KH, KM, LB, and CM conceptualised the research  
5  
6 379 design, drafted the research protocol, and are coordinating the project team. JE, ER, RF, DLC  
7  
8 380 provided expert advice and are lead site investigators. MO, NB, HS, and RK are responsible  
9  
10 381 for the acquisition of data and data monitoring. MV, NM, KM, RD, RL, MJ, RS, NA, NM,  
11  
12 382 MF, PF, and CL are collaborators and contributed with expert advice and funding  
13  
14 383 applications. LB advised on the trial design and was responsible for the sample size  
15  
16 384 calculation and statistical analysis methods. KH was responsible for the design of the  
17  
18 385 economic evaluation. KM was responsible for the design of the process evaluation. MO, DC,  
19  
20 386 RP, MC, MM, DH, LB, and KH are site investigators contributing to the implementation of  
21  
22 387 the model of care. All authors contributed to refinement of the study protocol and approved  
23  
24 388 the final manuscript.

25  
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27  
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29  
30 391 Early Career Fellowship. RB is funded by an NHMRC Senior Principal Research Fellowship.  
31  
32 392 CGM is funded by an NHMRC Principal Research Fellowship.

33  
34 393 **Study sponsor:** The University of Sydney, NSW 2006 Australia.

35  
36 394 **Competing interests:** None declared. Study sponsor and funders have no role in the study  
37  
38 395 design; collection, management, analysis, and interpretation of data; writing of the report; or  
39  
40 396 the decision to submit the report for publication.

41  
42 397 **Patient consent:** Consent of the clinician and patient participants will be obtained.

43  
44 398 **Ethics approval:** The study received ethical approval from the Sydney Local Health District  
45  
46 399 (RPAH zone) Ethics Committee, Sydney, Australia (X17-0043).

47  
48 400 **Provenance and peer review:** Not commissioned; externally peer reviewed.

49  
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55  
56 404 works on different terms, provided the original work is properly cited and the use is non-  
57  
58 405 commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

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**Table 1.** The key principles of the ACI model of care for acute low back pain




Principle 1	Assessment: history and examination
Principle 2	Risk stratification
Principle 3	Patient education
Principle 4	Active physical therapy encouraged
Principle 5	Begin with simple analgesic medicines
Principle 6	Judicious use of complex medicines
Principle 7	Cognitive behavioural approach
Principle 8	Only image those with suspected serious spinal pathology
Principle 9	Pre-determined times for review
Principle 10	Timely referral and access to specialist services

Source: NSW Agency for Clinical Innovation. Management of people with acute low back pain: model of care. Chatswood; NSW Health; 2016. 39 p, available at: <https://www.aci.health.nsw.gov.au/resources/musculoskeletal/management-of-people-with-acute-low-back-pain/albp-model>



**Table 2.** SHaPED trial design

Steps (clusters)	Year 1												Year 2						
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7
ED 1																			
ED 2																			
ED 3																			
ED 4																			

-  12-month retrospective baseline control period
-  4-week initial implementation intervention period
-  Sites continue with intervention plus follow-up period

For peer review only

**Table 3.** Medications per ATC classification

<b>Group</b>	<b>ATC code</b>
Analgesics	N02B
NSAIDs	M01A M02AA
Muscle relaxants	M03
Opioids	N02A N01AH
Neuropathic pain medicines	N03 N06A

ATC, Anatomical Therapeutic Chemical. NSAIDs, Non-steroidal anti-inflammatory drugs

For peer review only

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2  
3 **Supplementary Appendix 1. The SHaPED trial investigators**  
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5

6  
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9 Howard, Kirsten McCaffery, Laurent Billot, James Edwards, Eileen Rogan, Rochelle Facer,  
10 David Lord Cowell, Chris Maher.  
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12  
13

14  
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18  
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20  
21 Concord Repatriation General Hospital: Daniel Harrison, Leslie Barnsley.  
22  
23 Dubbo Base Hospital: Kristy Hatswell.  
24  
25

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27 Sydney Local Health District: Mauricio Oliveira, Noel Baidya, Hannah Storey, Rachael  
28 Knoblanche.  
29  
30  
31

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40 Sydney Health Partners: Nobby Alcala.  
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42 Macquarie University: Niamh Moloney.  
43  
44 The University of Sydney: Manuela Ferreira, Paulo Ferreira, Chris Lin.  
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**Supplementary Appendix 2.** SNOMED CT-AU (EDRS) codes related to low back pain

presentations

DESCRIPTION	CODES
<b>Low back pain with non-specific cause</b>	
Acute low back pain (finding)	278862001
Back pain complicating pregnancy (disorder)	91957002
Backache (finding)	161891005
Blunt injury to back (disorder)	424270008
Chronic back pain (finding)	134407002
Chronic low back pain (finding)	278860009
Coccyx sprain (disorder)	209571002
Complaining of low back pain (finding)	161894002
Degeneration of lumbar intervertebral disc (disorder)	26538006
Displacement of lumbar intervertebral disc without myelopathy (disorder)	20021007
Exacerbation of backache (finding)	135860001
Low back pain (finding)	279039007
Low back strain (disorder)	300956001
Lower back injury (disorder)	282766005
Lumbar spondylosis (disorder)	239880009
Lumbar sprain (disorder)	209565008
Mechanical low back pain (finding)	279040009
Pain in the coccyx (finding)	34789001
Sacral back pain (finding)	61486003
Spasm of back muscles (finding)	203095000
Sprain of ligament of lumbosacral joint (disorder)	209548004
Stiff back (finding)	249921008
Strain of back muscle (disorder)	262965006
Strain of tendon of back (disorder)	262975009
<b>Low back pain with neurological signs and symptoms</b>	
Acute back pain with sciatica (finding)	247366003
Acute sciatica (disorder)	307176005
Chronic sciatica (disorder)	307177001
Injury of lumbar nerve roots (disorder)	24300005
Injury of sciatic nerve (disorder)	86269002
Lumbago with sciatica (finding)	202794004
Lumbago-sciatica due to displacement of lumbar intervertebral disc (disorder)	46960006
Lumbar disc prolapse with radiculopathy (disorder)	202735001
Lumbar radiculopathy (disorder)	128196005
Sciatica (disorder)	23056005
Spinal stenosis of lumbar region (disorder)	18347007
<b>Low back pain due to serious pathology</b>	
Abscess of back (disorder)	309083007
Abscess of back, except buttock (disorder)	19284003
Cauda equina syndrome (disorder)	192970008
Closed fracture lumbar vertebra (disorder)	207957008
Collapse of lumbar vertebra (disorder)	308758008
Compression fracture of lumbar spine (disorder)	426646004
Concussion and edema of lumbar spinal cord (disorder)	212360005
Contusion of back (disorder)	11437003
Contusion of lower back (disorder)	284062002
Crush fracture of lumbar vertebra (disorder)	281933002
Disc prolapse with myelopathy (disorder)	202728009

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3	Discitis (disorder)	2304001
4	Fracture of coccyx (disorder)	125871005
5	Fracture of lumbar spine (disorder)	125608002
6	Fracture of lumbar spine and/or pelvis (disorder)	207986006
7	Injury of cauda equina (disorder)	230614002
8	Lumbar disc prolapse with myelopathy (disorder)	202731005
9	Multiple fractures of lumbar spine and/or pelvis (disorder)	207993005
10	Open dislocation of coccyx (disorder)	44237008
11	Open fracture of lumbar vertebra with spinal cord injury (disorder)	48956000
12	Open fracture of sacrum AND/OR coccyx with spinal cord injury (disorder)	65491009
13	Traumatic dislocation of joint of lumbar vertebra (disorder)	129166009
14	Traumatic dislocation of lumbosacral joint (disorder)	129161004
15		
16	SNOMED CT-AU (EDRS), Systematized Nomenclature of Medicine – Clinical Terms – Australian	
17	Version (Emergency Department Reference Set).	
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### Supplementary Appendix 3. SHaPED Implementation strategy and intervention description

The implementation plan for the Sydney Health Partners Emergency Department (SHaPED) trial has been adapted from: Jabbour M, Reid S, Polihronis C, Cloutier P, Gardner W, Kennedy A, Gray C, Zemek R, Pajer K, Barrowman N, Cappelli M. Improving mental health care transitions for children and youth: a protocol to implement and evaluate an emergency department clinical pathway. *Implement Sci.* 2016;11:90.

#### 1. Create implementation team:

- a) Obtain support from clinical leads and administration heads at the four emergency departments. Formalise a partnership agreement between institutions.
- b) Recruit and engage study champions at each emergency department. Team members to include: emergency physicians, physiotherapists, nurses, managers, and clinical educators.
- c) Develop a working group and form a steering committee at each emergency department to provide oversight on implementation progress.
- d) Establish meeting schedule: local steering committee to meet twice a week and report to study supervisors every week during the implementation period.

#### 2. Assessment:

- a) Review and discuss the existing models of care for low back pain at the four emergency departments and recommend adaptation to facilitate adoption of the new model.
- b) Conduct an environmental assessment and identify typical pathway of care for a patient presenting with low back pain at each emergency department.
- c) Identify practices and processes that require development or change in order to support the implementation strategy.
- d) Identify internal and external stakeholders who will be impacted by the new model and therefore require education and support to implement it.

#### 3. Plan strategy for change

- a) Identify leadership support required for implementation phase.
- b) Identify and engage influential clinical champions who will effectively drive change.
- c) Revise or develop policies as needed.
- d) Develop a knowledge translation strategy to support practice change, such as shared staff meetings, educational rounds, peer-to-peer mentoring.

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3 e) Identify factors that will support practice change, such as engaging all potential  
4 stakeholders, scheduling champions and clinicians to enable attendance at meetings and  
5 face-to-face education sessions, facilitating the development of relationships between  
6 emergency physicians and other clinical staff, conducting audits or monitor specific data  
7 indicators that will support practice change.  
8  
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10  
11 f) Identify factors that may create a barrier for practice change in the emergency department,  
12 including attitudes and beliefs about low back pain management, and lack of clinician  
13 expertise/comfort to treat this population.  
14  
15 g) Develop strategies to manage barriers, such as communication, education, opportunities to  
16 develop relationships within and between clinicians and service provider.  
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#### 22 **4. Implementation:**

- 23  
24 a) Provide clinician information package:  
25  
26 • Deliver printed copies of the ACI Model of care (full version and executive summary) to  
27 clinician participants.  
28  
29 • Create a list of “red flags” to screen for serious pathologies from the ACI Model of care  
30 and deliver a printed version to clinician participants.  
31  
32 • Create posters outlining the ‘10 principles’ of the ACI model of care, as well as the  
33 clinical pathways and place them at key locations of each participating emergency  
34 department.  
35  
36 • Inform clinician participants about and provide them access to online videos and other  
37 printed (such as the ACI consumer information booklet) and electronic educational  
38 materials to educate patients with low back pain at emergency discharge.  
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45 b) Provide patient information package:  
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47 • Encourage clinician participants to provide a printed copy of the ACI consumer  
48 information booklet to patients with low back pain during emergency department visit.  
49  
50 • Where most of the patient population do not speak English, encourage clinician  
51 participants to provide a copy of the Emergency Care Institute (ECI) Patient Factsheet for  
52 low back pain (available in six languages).  
53  
54 • Create posters outlining four myths of low back pain management and placed them at the  
55 reception area of each emergency department.  
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3 c) Deliver clinician education:  
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- 5 • Educational seminars will be delivered by an experienced clinician (Dr Chris Needs) at  
6 week 1 of the intervention period. Booster sessions in the first week will also be conducted  
7 by local investigators (such as Directors of Emergency Medicine, clinical educators) as  
8 required, as well as in weeks 2 to 4.  
9  
10 • The educational seminars will be conducted primarily during the existing regular clinical  
11 staff meetings, but additional sessions will be scheduled to reach all emergency clinicians.  
12 The format of the seminars consists of a mini-lecture and interactive group discussions  
13 and will last for 40 to 60 minutes.  
14  
15 • During the educational seminars, clinician participants will be trained on history taking  
16 and examination of patients with low back pain, on how to use SNOMED diagnosis codes,  
17 and will be encouraged to follow the recommendations in the ACI model of care to  
18 manage these patients, with focus on the key outcomes of this study (that is, imaging,  
19 opioids, and inpatient admission rates).  
20  
21 • During weeks 1 to 4, individual meetings with clinician participants will be scheduled as  
22 required to cover the key messages and principles outlined in the ACI model of care.  
23 There will be at least one educational outreach visit to each clinician in weeks 1 to 4 and  
24 they can request additional if they have any concerns. Clinician participants can also seek  
25 advice from clinical educators by email.  
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38 d) Develop audit and feedback focussed on study outcomes  
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- 40 • Each emergency department and clinician participant will receive at the first  
41 educational seminar session an emergency department level feedback on the 12-  
42 month retrospective data performance against the outcomes of this study (that is,  
43 imaging, opioids, inpatient admission rates).  
44  
45 • This audit and feedback approach will be repeated each month after the  
46 implementation of the model of care during the regular emergency staff meetings  
47 until the end of the follow-up period.  
48  
49 • Clinician participants at the Sydney Local Health District (SLHD) will be encouraged  
50 to use the SLHD Targeted Activity and Reporting System (STARS) to monitor the  
51 emergency department performance during and after the implementation period.  
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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents\*

Section/item	Item No	Description	Addressed on page number
<b>Administrative information</b>			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2, 6_____
	2b	All items from the World Health Organization Trial Registration Data Set	N/A_____
Protocol version	3	Date and version identifier	Footer_____
Funding	4	Sources and types of financial, material, and other support	14_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	14, Appendix 1_
	5b	Name and contact information for the trial sponsor	14_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	14_____
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Appendix 1_____

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**Introduction**

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4, 5_____
	6b	Explanation for choice of comparators	N/A_____
Objectives	7	Specific objectives or hypotheses	5, 6_____
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6_____

**Methods: Participants, interventions, and outcomes**

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6, 7_____
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7, 8_____
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	7, 8, 12_____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A_____
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9, 10_____
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Table 2_____

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3	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	8, 9_____
4				
5	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	10, 11_____
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7				

### 8 **Methods: Assignment of interventions (for controlled trials)**

#### 9 Allocation:

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12	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	7_____
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17	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	7_____
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21	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7_____
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24	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8, 10_____
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27		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A_____
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### 31 **Methods: Data collection, management, and analysis**

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33	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	10, 11_____
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38		18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	11_____
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Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	11_____
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Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	11_____
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	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	11, 12_____
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	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	N/A_____
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**Methods: Monitoring**

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Appendix 1_____
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	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A_____
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Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A_____
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Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A_____
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**Ethics and dissemination**

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	12, 13_____
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Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	13_____
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1				
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3	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7, 11, 14_____
4				
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6		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A_____
7				
8	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	In ACTRN _____
9				
10				
11	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	14_____
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14	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14_____
15				
16				
17	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A_____
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20	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	In ACTRN _____
21				
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25		31b	Authorship eligibility guidelines and any intended use of professional writers	Appendix 1_____
26				
27		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A_____
28				
29	<b>Appendices</b>			
30				
31	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A_____
32				
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34	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A_____
35				
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37 \*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items.  
 38 Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons  
 39 "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.  
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