

# Can patients identify what triggers their back pain? Secondary analysis of a case-crossover study

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## Abstract

The aim of this case-crossover study was to investigate the extent to which patients can accurately nominate what triggered their new episode of sudden-onset acute low back pain (LBP). We interviewed 999 primary care patients to record exposure to 12 standard triggers and also asked the patients to nominate what they believed triggered their LBP. Exposure to the patient-nominated trigger during the case window was compared with exposure in the control window. Conditional logistic regression models were constructed to quantify the risk of LBP onset associated with the patient-nominated trigger. Sensitivity analyses were conducted varying the duration and timing of case/control windows. We compared the extent to which patient-nominated triggers matched standard triggers. The odds ratios for exposure to patient-nominated triggers ranged from 8.60 to 30.00, suggesting that exposure increases the risk of LBP. Patients' understanding of triggers however seems incomplete, as we found evidence that while some of the standard triggers were well recognised (such as lifting heavy loads), others (such as being distracted during manual tasks) were under-recognised as possible triggers of an episode of LBP. This study provides some evidence that patients can accurately nominate the activity that triggered their new episode of sudden-onset acute LBP.

**Keywords:** Low back pain, Risk factors, Observational

## 1. Introduction

Low back pain (LBP) is the leading cause of activity limitation and work absence throughout much of the world.<sup>9</sup> As reported in the Global Burden of Disease Study 2010 (GBD 2010), LBP is 1 of the 10 leading causes of years lived with disability.<sup>25</sup> Along with the high prevalence and burden on individuals, the costs associated with LBP are very large.<sup>3</sup> Globally, costs due to work productivity losses along with health care expenditure are responsible for the bulk of the societal cost of LBP.<sup>3</sup> Despite the high prevalence and costs, there is limited knowledge of what triggers an episode of LBP.

Low back pain is a complex condition; many risk factors are believed to contribute to its onset.<sup>12</sup> A range of biomechanical, psychological/psychosocial, and individual characteristics has been identified as risk factors for LBP.<sup>6,11,15</sup> Some risk factors such as being overweight involve prolonged exposure, whereas triggers such as lifting awkwardly involve short-term transient exposure just before the onset of LBP. Understanding factors that

trigger an episode of LBP may provide important insights into the prevention and management of this condition.<sup>23,24</sup>

Patients' views represent an important field of health care research.<sup>18</sup> Until now, research into patients' views regarding factors that trigger an episode of LBP has been conducted using qualitative methods.<sup>5,13,18,20</sup> In these studies, participants displayed biomedical beliefs about triggers of LBP, typically attributing pain to structural/anatomical vulnerability of the spine and exposure to heavy manual tasks. However, these results are based on qualitative studies examining expectations and beliefs about the causes of LBP. To our knowledge, no study has used a quantitative paradigm to evaluate whether patients can accurately identify what triggered their episode of LBP. Should it be demonstrated that patients can accurately identify these triggers then clinicians could apply this information when developing individual treatment and prevention programmes.

The aim of this study was to investigate the extent to which patients can accurately nominate what has triggered their new episode of sudden-onset acute LBP. We hypothesised that in general, patients would be able to identify the trigger for their LBP but that there may be some types of triggers that are missed (ie, under-recognised) and others that are over-recognised.

## 2. Methods

### 2.1. Study design

Data for this study were obtained from the TRIGGERS for LBP study.<sup>22,23</sup> TRIGGERS is a case-crossover study that investigated the increase in risk of a sudden episode of LBP associated with transient exposure to 12 standard triggers (eg, heavy loads, awkward posture, objects not close to the body, live people or animals, unstable/unbalanced/difficult to grasp or hold loads, vigorous physical activity, moderate physical activity, slip/trip/fall,

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sexual activity, consumption of alcohol, distracted during an activity or task, and fatigued/tired). The increase in risk was assessed by comparing exposure to these standard triggers immediately before pain onset with exposure 24 hours before pain onset in people presenting to primary care with an acute episode of back pain. The 12 standard triggers were obtained from the list of hazardous tasks provided in the National Code of Practice.<sup>19</sup> Additionally, a number of factors that had been previously identified as triggers in occupational injury studies, but never evaluated in the area of back pain, were included. Exposure information was collected during a phone interview for each participant. After collecting information on exposure to the 12 standard triggers, each patient was asked to nominate, using free text, what they believed was the trigger for their episode of LBP (ie, patient-nominated trigger).

We evaluated the accuracy of the patient-nominated triggers in 3 ways. First, we quantified the risk of developing a new episode of LBP associated with exposure to the patient-nominated triggers without distinguishing between the various types of triggers nominated. This tested the hypothesis that if patients could accurately identify the trigger for their LBP, we would expect to see a positive measure of association (high odds ratio [OR]) for the patient-nominated trigger. Second, we repeated this analysis but only including the subset of participants for whom the nominated trigger was 1 of the 12 standard triggers. Third, we compared the distribution of exposure to patient-nominated triggers with the distribution of exposure to the corresponding standard triggers. At the group level, we expected patients to nominate more frequently the standard triggers we had previously shown to be strongly associated with episodes of LBP and nominate less frequently the triggers with a weaker or no association (OR close to 1). The third analysis allowed us to estimate whether patients underestimate or overestimate the harmful effects of certain triggers.

## 2.2. Participants

Consecutive patients with a new episode of acute LBP, aged 18 years or older, of either gender, were recruited. The study recruited from primary care clinics in New South Wales, Australia, between October 2011 and November 2012. A new episode of LBP was defined as a primary complaint of pain between the 12th rib and the buttock crease, with or without leg pain, causing the patient to seek health care or take medication, and preceded by a period of at least 1 month without pain.<sup>4</sup> Patients presenting with first-ever episodes or recurrent episodes were eligible as long as they fitted the definition of a new episode of LBP. To be eligible to enter the study, participants had to meet all of the following criteria: (1) comprehend spoken English, (2) primary complaint of pain in the area between the 12th rib and the buttock crease, with or without leg pain, (3) pain of least moderate intensity during the first 24 hours of the episode (assessed using a modified version of item 7 of the SF-36), (4) presentation for treatment within 7 days from the time of pain onset. Patients with metastatic, inflammatory, or infectious disease of the spine, cauda equina syndrome, and spinal fracture were excluded from the study.<sup>10</sup> All participants gave written informed consent for participation. Ethical approval for the study was granted by The University of Sydney Human Research Ethics Committee (protocol number 05-2011/13742).

## 2.3. Study interview

Trained research staff used an interview script to collect socio-demographic and clinical characteristics from the participant as

well as data on exposure to a variety of possible triggers. During the interview, participants were asked to identify the date and time of pain onset. The interview script was piloted on 20 subjects with back pain and adjustments made to improve clarity and participant recall. Design features were included to minimise recall bias. For instance, to be eligible, participants had to present within 7 days of the onset of back pain, as this short time between the event and reporting of the event would facilitate recall of activities. In addition, trained research staff asked participants to use prompts such as referring to their agenda, calendar, and/or smartphones to enhance their memory of the activities they performed in the days before the onset of their LBP.

Assisted by research staff, participants were then asked to report exposure to each of the 12 standard triggers, including time of occurrence and duration, over the 96 hours preceding the onset of LBP. The time period of 96 hours was used so that participants, clinicians, and interviewers would remain blinded to the case and control windows. This was done to reduce any differential misreporting by patients or interviewers to fit case and control windows. The time and duration of exposure for each standard trigger was recorded.

In the final portion of the interview, participants were asked to nominate what they thought might have triggered their LBP (ie, patient-nominated trigger) with the following question: “What do you think may have triggered your LBP?” The exposure to the patient-nominated trigger was recorded, and it was noted whether this occurred on the day of LBP, the day before, 2 days before, or 3 days before.

## 2.4. Data coding

The patient-nominated triggers were then matched to the 12 standard triggers and coded by 2 independent researchers. A patient-nominated trigger could match none, 1, or more of the 12 standard triggers. Any discrepancies were resolved by discussion and consensus. If consensus could not be obtained, a third researcher made the final decision.

The purpose of matching the patient-nominated triggers to the standard triggers was to allow for a more precise determination of the duration of exposure to a patient-nominated trigger. This was because in the original TRIGGERS study,<sup>23</sup> exposure to standard triggers was recorded in 10-minute time epochs, whereas exposure to patient-nominated triggers was only recorded in days.

## 2.5. Statistical analysis

Conditional logistic regression models were constructed to quantify the risk of LBP onset associated with each patient-nominated trigger, where each participant represented a matched set of data for case and control exposures. The time periods of occurrence and duration of exposure were similar for the original TRIGGERS study and the current study. In the original TRIGGERS study, the frequency of exposure to each trigger was calculated for the case (2 hours before the onset of back pain) and 2 control windows (24–26 hours and 48–50 hours before the onset of back pain, respectively). In the current study, we performed 2 analyses. First, we built a model comparing exposure to the patient-nominated trigger on the day of the event (case window) with exposure 2 days before the event (control window). Sensitivity analyses were also conducted with the control window being 3 days before the event. Windows of 24-hour duration were used in this analysis, as we did not know the precise time of day the participant was exposed to the patient-nominated trigger. By selecting the control window 2 days before, we ensured that there

was at least 24 hours between exposures in the case and control windows. We did not select a control window 1 day before because exposure at the end of this control window and exposure at the beginning of the case window would not be separated by a full 24 hours (theoretically, they may be separated by less than a minute). Risk of an episode of sudden acute LBP was expressed using ORs and 95% confidence intervals (CIs).

A second analysis was conducted on the subset of participants for whom the patient-nominated trigger matched 1 of the 12 standard triggers. This allowed for more precise estimation of exposure period, in 10-minute time epochs, and therefore the analysis included 2-hour case windows immediately preceding the LBP onset and 2-hour control windows occurring 24 hours before the onset of LBP (eg, 24-26 hours). This subgroup analysis was only performed where there was sufficient endorsement for a trigger (ie, minimum number of 50 participants per analysis).

To evaluate whether patients underestimate or overestimate the harmful effects of certain triggers, the distribution of exposure to patient-nominated triggers was compared with the distribution of exposure to the corresponding standard triggers previously reported in the original TRIGGERS study.<sup>23</sup>

### 3. Results

Of the 999 participants included in the original TRIGGERS study,<sup>23</sup> a total of 679 (67.9%) patients nominated an activity as responsible for their episode of LBP. Analyses were made only with patients who identified 1 or more of the 12 standard triggers (Fig. 1). The characteristics of the participants who nominated an activity are presented in Table 1. Just over half the sample were male (58.6%), with a mean (SD) age of 44 years (13.8). In the first 24 hours after pain onset, the majority of participants rated the pain as severe (50.1%) and the mean (SD) duration of the current episode was 4.8 (2.7) days. Patients typically presented to health care a mean (SD) of 3.0 (2.1) days from the pain onset.

The frequency of exposure to patient-nominated triggers on the day of the LBP onset (case window) and 2 days (first control window) or 3 days (second control windows) preceding the pain episode with the associated ORs are presented in Table 2. For all analyses, exposure to the patient-nominated trigger increased the odds of developing an acute episode of LBP. For the primary analysis, the OR (95% CI) was 8.60 (6.68-11.07), and for the secondary analyses, the OR (95% CI) was 11.96 (8.94-16.01).

The results of the second analysis, using a more precise timing of exposure to a patient-nominated trigger, are shown in Table 3. Exposure frequencies were too small for some triggers to be sensibly included in the regression analyses. For all 5 triggers included in the regression analysis, participants were more likely to be exposed to the patient-nominated trigger in the case window (ie, first 24 hours preceding pain onset) than in the control window. For example, in many cases, patients nominated triggers, which had been previously found in the original TRIGGERS study<sup>23</sup> to be associated with large ORs (eg, heavy lifting), suggesting that patients' perceptions are well aligned with the evidence. However, there were a few triggers for which we found evidence of an increased risk in the main study, but were rarely endorsed by patients as a trigger in our study. For instance, being distracted during a manual task and manual tasks involving an object not close to the body were infrequently nominated by

**Table 1**  
**Characteristics of the participants (n = 679).**

Characteristics	Participants
Age, mean (SD), y	44.7 (13.8)
Male sex, n (%)	398 (58.6)
Height, mean (SD), cm	172.9 (10.4)
Weight, mean (SD), kg	79.5 (18.1)
Body mass index, mean (SD), kg/m <sup>2</sup>	26.4 (5.2)
Duration of current episode, mean (SD), d	4.8 (2.7)
Number of previous episodes, mean (SD)	5.9 (14.7)
Days to seek care, mean (SD)	3.0 (2.1)
Days from presentation to health care and interview, mean (SD)	1.9 (2.0)
Days of reduced activity, mean (SD)	2.3 (2.1)
Pain scores (0-10), mean (SD)	5.3 (2.1)
Currently taking medication, n (%)	314 (46.2)
Workers' compensation, n (%)	44 (7.3)
If in paid employment, what do you do for a living, n (%)	
Not employed	115 (16.9)
Clerical and administrative worker	69 (10.2)
Community and personal service worker	33 (4.9)
Labourer	23 (3.4)
Machinery operator and driver	25 (3.7)
Manager	106 (15.6)
Professional	220 (32.4)
Sales worker	27 (4.0)
Technician and trade worker	61 (9.0)
Pain location, n (%)	
Upper back	39 (5.7)
Lower back	679 (100)
Left thigh (back)	65 (9.6)
Left leg (back)	23 (3.4)
Right thigh (back)	73 (10.8)
Right leg (back)	32 (4.7)
Right thigh (front)	22 (3.2)
Right leg (front)	6 (0.9)
Left thigh (front)	25 (3.7)
Left leg (front)	7 (1.0)
Pain severity in the first 24 h, n (%)	
Moderate	232 (34.2)
Severe	340 (50.1)
Very severe	107 (15.8)
Pain interfering with work in the first 24 h, n (%)	
Not at all	14 (2.1)
A little bit	65 (9.5)
Moderately	159 (23.4)
Quite a bit	254 (37.4)
Extremely	187 (27.5)

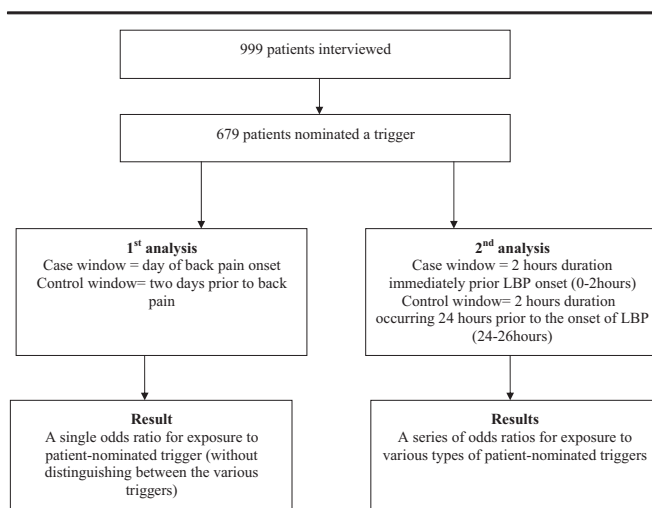


Figure 1. Study flowchart.

Body mass index: weight in kilograms divided by the square of the height in metres.

**Table 2****Exposure frequency and ORs for exposure to patient-nominated triggers (case window vs control window): primary analysis and sensitivity analyses (n = 679).**

Case window (0–24 h), n (%)	First control window (0–24 h), n (%)	OR (95% CI)	P
Main analysis			
679 (68.0)	170 (17.0)	8.60 (6.68–11.07)	<0.0001
Sensitivity analysis			
679 (68.0)	142 (14.2)	11.96 (8.94–16.01)	<0.0001

CI, confidence interval OR, odds ratio.

patients as the cause of the back pain; however, in the original TRIGGERS study,<sup>22</sup> exposure to these triggers was shown to significantly increase the risk of LBP and patients were frequently exposed to these triggers. The ORs ranged from 9.00 to 30.00, providing evidence suggesting that exposure to these patient-nominated triggers was indeed harmful.

In **Table 4**, columns 2 to 4 show the exposure frequencies and ORs for the 12 standard triggers (as previously reported in Ref. 23) based on the full sample of 999 participants. Column 5 shows the proportion who nominated the standard trigger as the cause of their LBP. It can be seen that patients frequently nominated some of the triggers with high ORs (eg, heavy loads, awkward postures) and infrequently nominated some of the triggers with ORs close to 1 (eg, consumption of alcohol). This distribution of responses suggests that they appropriately recognised risk when nominating (or not nominating) this set of triggers. In contrast, for some other triggers (eg, being fatigued or tired), the results suggest that patients may underestimate the risk associated with that trigger (analogous to a false-negative result in a diagnostic study).

## 4. Discussion

### 4.1. Statement of principal findings

This study provides evidence that patients can accurately nominate an activity that triggered their sudden-onset acute LBP. The OR for association between patient nominated triggers and risk of developing acute LBP was 8.60 in the primary analysis and 11.96 in the sensitivity analysis, suggesting that patients can identify risk behaviours well. When we repeated the analyses and focussed on specific types of triggers, and used a more precise time window, the ORs ranged from 9.00 to 30.00, again suggesting that patients had in fact identified substantially risky triggers for a new episode of LBP. However, patients' understanding of triggers seems incomplete, as we also found

evidence that certain types of triggers were under-recognised as increasing the risk of an episode of LBP. Triggers such as being distracted during a manual task and manual tasks involving an object not close to the body were infrequently nominated as the cause of the LBP; however, in the original TRIGGERS<sup>22</sup> study,<sup>23</sup> these triggers had high ORs significantly increasing the risk of LBP and patients were frequently exposed to these triggers. This pattern of responses suggests that the risk associated with exposure to these specific triggers is not widely appreciated by patients. There were no examples of triggers with ORs close to 1 that were frequently nominated (ie, a false positive), but there was limited potential for us to identify false positives, as only 2 of the 12 standard triggers had ORs close to 1 in the original study.

### 4.2. Strengths and weaknesses of the study

A strength of the study was that we enrolled a large representative sample of patients seeking primary care for an acute episode of LBP. We also used the case-crossover design to provide estimates of the transient increase in risk of LBP associated with exposure to various triggers. Case-crossover studies provide perfect matching of known and unknown confounders between cases and controls. Moreover, as in case-crossover studies, participants are only compared with themselves at 2 different times (ie, case vs control windows); individual differences such as age and past pain experience, which could affect participants' recall of symptoms and activities, would impact the case and control windows to the same extent, not influencing therefore the association between exposure and event. Another strength of this study is the fact that we have minimised the recall period to a maximum of 14 days. This is substantially less than many studies including self-report outcomes in the pain literature, for example, the standard version of the SF-36 has a 1-month recall period. The choice of case and control windows can be

**Table 3****Exposure frequency and ORs for nominated trigger: second analysis with more precise timing of exposure\* (n = 679).**

Triggers	Case window (0–2 h), n (%)	First control window (24–26 h), n (%)	OR (95% CI)	P
Manual tasks involving				
Heavy loads	106 (56.7)	21 (11.2)	10.44 (5.27–20.70)	<0.001
Awkward posture	73 (62.4)	14 (12.0)	15.75 (5.73–43.27)	<0.001
Objects not close to the body	4 (100)	1 (25.0)	—	—
Live people/animals	35 (60.3)	13 (22.4)	—	—
Unstable/unbalanced/difficult to grasp or hold	3 (37.5)	0 (0.0)	—	—
Vigorous physical activity	41 (46.6)	6 (6.8)	9.75 (3.48–27.28)	<0.001
Moderate physical activity	42 (30.4)	10 (7.3)	9.00 (3.20–25.29)	<0.001
Slip/trip/fall	30 (75.0)	1 (2.5)	30.00 (4.09–219.98)	0.001
Consumption of alcohol	0 (0.0)	0 (0.0)	—	—
Sexual activity	1 (3.3)	0 (0.0)	—	—
Distracted	0 (0.0)	0 (0.0)	—	—
Fatigued/tired	2 (14.3)	2 (14.3)	—	—

\* Analysis was conducted on the subset of participants for whom the patient-nominated trigger matched 1 of the 12 standard triggers.

CI, confidence interval; OR, odds ratio.



**Table 4****Comparison of risk data from the original TRIGGERS study and participants' endorsement of a trigger as the cause of their back pain.**

Triggers	Case window (0-2 h), n (%)	First control window (24-26 h), n (%)	OR*	Nominated trigger, n (%)
Heavy loads	179 (17.9)	64 (6.4)	4.97	187 (18.7)
Awkward posture	274 (27.4)	70 (7.0)	8.03	117 (11.7)
Objects not close to the body	40 (4.0)	14 (1.4)	6.20	4 (0.4)
Live people/animals	86 (8.6)	62 (6.2)	5.80	58 (5.8)
Unstable/unbalanced/difficult to grasp or hold	52 (5.2)	19 (1.9)	5.13	8 (0.8)
Vigorous physical activity only	105 (10.5)	44 (4.4)	3.90	87 (8.7)
Moderate or vigorous physical activity	225 (22.5)	129 (12.9)	2.70	140 (14.0)
Slip/trip/fall	37 (3.7)	1 (0.1)	—	40 (4.0)
Consumption of alcohol	13 (1.3)	9 (0.9)	1.50	1 (0.1)
Sexual activity	8 (0.8)	11 (1.1)	0.73	3 (0.3)
Distracted	30 (3.0)	6 (0.6)	25.00	1 (0.1)
Fatigued/tired	118 (11.8)	69 (6.9)	3.72	14 (1.4)

Data are exposure frequency and ORs for the 12 standard triggers and percentage of sample who nominated that trigger (n = 999).

\* Based on case and control windows of 2-h duration.

OR, odds ratio.

interpreted as limitation. However, to minimise this limitation, sensitivity analyses were conducted varying the window durations and obtained very similar ORs. Other studies<sup>1,14,17,22</sup> have used this design to quantify the risk associated with transient exposures and published their findings in prestigious journals, suggesting that the methodology is rigorous and well accepted. Another limitation of the study was that participants were seeking treatment for a new episode of acute LBP, and it is unclear whether similar results would have been observed for people not seeking care for LBP or those with persistent symptoms.

#### 4.3. Strengths and weaknesses in relation to other studies, discussing important differences in results

To our knowledge, this is the first study to test the accuracy of patients' views on triggers of acute LBP. Previous qualitative studies<sup>2,5,13,18,21</sup> have evaluated patients' views of potential triggers for an episode of LBP, but these had never been tested before as potential triggers. In these studies, the majority of the participants attributed pain to damage of the disc or wear and tear of the spine. Only 1 study<sup>20</sup> has considered patients' views on general risk factors for LBP. In this study, pairs of twins discordant for LBP were identified and interviewed about what they believed to be responsible for their own or their twin's LBP status. Twins' responses to the closed questioning showed that the factors more frequently perceived as possible reasons for their differences in LBP status were related to physical loading of the spine, such as performing work with heavy loads. A comparison of our findings with previous research would suggest that patients under-recognise some types of triggers. Our study found that physical triggers, such as manual tasks involving heavy loads and awkward postures, were more frequently endorsed by patients as triggers of LBP than other behavioural and psychological factors. While there is strong research demonstrating that some behavioural and psychological factors increase the risk for LBP,<sup>8,10</sup> the 3 we evaluated (consumption of alcohol, distraction, fatigue) were rarely endorsed by patients in this study. This is in accordance with previous studies that have shown that most patients hold biomechanical views about causes of LBP.<sup>2,13,18</sup> Patients seem to have developed a set of narrative strategies that are intended to reduce the risk of being classed as "psychological" cases. Therefore, they begin by emphasising biomechanical causes for their LBP.<sup>16</sup> Patients also seemed to under-recognise certain risky lifting tasks (eg, of the 40 people who were exposed to the trigger

"lifting objects not close to the body" in the case window [ie, immediately before pain onset], only 4 attributed this as a potential trigger for their pain onset). A similar pattern occurred with "feeling fatigued or tired", "being distracted", and engaged in "manual tasks involving unstable/unbalanced/difficult to grasp or hold objects". These results suggest that patients' appreciation of risk factors for LBP is incomplete.

#### 4.4. Interpretation of the study: possible explanations and implications for clinicians and policymakers

Patients' ability to identify triggers for LBP is likely informed by their life experiences including previous experience of LBP, their education and beliefs, and worksite training.<sup>2,5</sup> Understanding patients' views strengthens support for previously identified triggers and highlights other relevant risk factors not previously considered as triggers. Our results also indicate some triggers that seem under-recognised and where greater emphasis may be needed in patient education and training. There may be value in clinicians extending the advice they give to patients on how to reduce exposure to the triggers that the patient recognises but, more importantly, to the triggers that they do not typically recognise. Particular emphasis should be placed on the influence of triggers such as distraction and fatigue and more complex forms of manual handling, which are not widely recognised as risky. We did not find any examples of false-positive beliefs about triggers, which is interesting because persistence of an episode of LBP has been linked to erroneous beliefs about pain and physical activity.<sup>7</sup> However, given that we only considered 12 standard triggers, and only 2 were not shown to increase risk, we acknowledged that we had limited ability to investigate this issue.

#### 4.5. Unanswered questions and future research

As this was a reanalysis of an existing data set, we were only able to consider the 12 standard triggers evaluated in the original TRIGGERS study. Examining a different set of triggers would be an important extension of our research. While our study focussed on identification of triggers for an acute episode of LBP, future studies should investigate triggers for exacerbations (or remissions) of persistent LBP. In our view, the most important direction for future research would be to investigate whether this novel information on triggers can be used to develop effective prevention strategies for LBP.

## Conflict of interest statement

The authors have no conflicts of interest to declare.

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Ethical approval for the study was granted by The University of Sydney Human Research Ethics Committee (protocol number 05-2011/13742).

Data sharing: No additional data available.

All authors affirm that the article is an honest, accurate, and transparent account of the study being reported and that no important aspects of the study have been omitted.

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All authors were involved in the design of the study. PP and DS prepared and cleaned the data. QL performed the statistical analysis. PP, MLF, DS, and CM wrote the first draft. All authors contributed to further drafts. All authors had full access to the data, specifically, the statistical reports and tables arising from the data, and take responsibility for integrity of the data and accuracy of the data analysis. All authors have approved the final version of the manuscript submitted for publication.

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