(C)onsumer focused (E)d ucation on p(A) racetamol (S)ide (E)ffects, i(N)ad equate (O) utcomes and (W)eaning (CEASE NOW) for individuals with low back pain: results of a feasibility study

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ABSTRACT

Objectives To determine the feasibility of a patient-education booklet to support patients with low back pain (LBP) to reduce paracetamol intake.

Design Single group, repeated measures feasibility study.

Setting Community.

Participants Adults experiencing LBP of any kind and self-reporting consumption of paracetamol for LBP weekly for at least 1 month were invited to participate.

Intervention Participants received a patient-education booklet 1 week after the baseline measures were collected. The intervention was designed to change beliefs, increase knowledge and self-efficacy to deprescribe paracetamol for their LBP and create discussion with a health professional through the mechanisms of motivation, capacity and opportunity.

Primary outcome measures Feasibility of recruitment procedures, data collection and acceptability of the intervention.

Secondary outcome measures Changes in motivation, self-efficacy, opportunity to deprescribe paracetamol for their LBP, paracetamol usage and LBP clinical outcomes at baseline, 1-week and 1-month follow-up.

Results A total of 24 participants were recruited into the study within the timeframe of 3 months from study advertisement and all completed the study follow-up. There were no missing data for any outcome measure across all follow-up periods. Twenty-two (91.6%) participants were willing to participate in a future randomised control trial (RCT) and over 60% of participants responded positively to questions regarding acceptability of the patient-educational booklet. Overall, at the 1-month follow-up, approximately two thirds (15/24) of participants had an increase in motivation and self-efficacy scores and had discussed or intended to discuss their paracetamol use for LBP with a health professional.

Conclusions The results of this study demonstrate that the patient-education booklet is feasible to implement, and both the intervention and study design were well-received by participants. This study supports the undertaking an RCT to assess the effects of the patient-education booklet on deprescribing paracetamol in people with LBP.

STRENGTHS AND LIMITATIONS OF THIS STUDY
⇒ Recruitment was facilitated by Musculoskeletal Australia and painaustralia.
⇒ This study had no missing data or loss to follow-up, with a follow-up rate of 100%.
⇒ No causal links can be made between the intervention and our findings as there was not a control group for comparison.
⇒ The follow-up period was short (1 month), thus it is unknown whether participants were successful in maintaining their reduction of paracetamol use for their low back pain in the long term.
⇒ Data were not collected on other types of analgesic use throughout the study, therefore there is potential that some participants may have reduced their paracetamol dosage, but started or increased dosage of another analgesic.

INTRODUCTION
Currently, many international clinical guidelines in the USA, UK, Germany, Denmark and Belgium no longer recommend the use of paracetamol (acetaminophen) for individuals with low back pain (LBP) due to the lack of clinical benefits and emerging links with adverse events associated with the medication.1 2 However, paracetamol remains one of the most commonly used analgesics to manage LBP worldwide, with between 50% and 95% of LBP sufferers across Australia, USA and Europe taking paracetamol.3–9 In Australia, this represents a heavy economic burden on individuals and society, as approximately $1 billion dollars per annum spent on LBP treatment is associated with analgesics such as paracetamol.10 Previous studies have highlighted that consumers lack knowledge and understanding regarding the possible harms when taking paracetamol, with up to...
80% of paracetamol users being unaware of the potential for adverse effects, including cardiovascular damage, liver toxicity and risk of overdosing.\textsuperscript{11,12} It is paramount that LBP sufferers are educated and supported to engage in safer and more effective alternatives to paracetamol to manage their LBP.

Previous studies have shown that educational interventions can successfully increase participants' self-efficacy and motivation to deprescribe non-steroidal anti-inflammatory drugs (NSAIDs), opioids and benzodiazepines.\textsuperscript{13,14} No previous study has investigated the feasibility of a patient-education booklet for individuals using paracetamol to manage their LBP. Additionally, no existing research has examined whether consumer-targeted interventions can change behaviour and result in deprescribing paracetamol for individuals with LBP.\textsuperscript{15}

The aim of this study was to investigate the feasibility of a patient-education booklet for people with LBP to increase their motivation and self-efficacy to reduce paracetamol use and engage in safer and more evidence-based LBP management strategies. In particular, the study aimed to determine the acceptability of the intervention, the feasibility of recruitment, data collection and outcome measure completion, and the willingness of participants to enrol in a randomised control trial (RCT).

\section*{Methods}

\subsection*{Design}

This study employed a single group, repeated measures design. The study was conducted in Sydney, Australia and the study protocol has been published.\textsuperscript{16}

\subsection*{Patient and public involvement statement}

Consumer representatives from painaustralia and Musculoskeletal Australia were involved in the design of the feasibility study and intervention in an iterative process in the early stages of conceptualisation prior to conducting the study. Additionally, we plan to disseminate the findings of this research to many patients and the public through consumer pain groups such as painaustralia and Musculoskeletal Australia, Consumer Health Forum, Australia Pain Management Association, Dragon Claw, Your Life Choices and Seniors Card.

\section*{Study overview}

Partnerships to support study implementation were developed with two large consumer groups: Musculoskeletal Australia and painaustralia. Musculoskeletal Australia and painaustralia represent over 4 million Australians living with musculoskeletal conditions and pain. These organisations assisted with recruitment by advertising the study to individuals subscribed to their database through their weekly newsletters. Only interested participants meeting the inclusion criteria and who provided online-signed informed consent were included in the study. Following written informed consent, participants received an email from the research team containing a secure link to complete the baseline questionnaire. Once completed, participants received the patient-education booklet via their preferred medium (physical mail, email or web link). One week and 1 month after receiving the patient-education booklet, participants received an email containing a secure link to complete follow-up questionnaires. On completing the 1-month follow-up questionnaire, participants were invited to participate in a telephone interview to gather their opinion on the usability and acceptability of the patient-educational booklet and qualitative aspects of the study (ie, ease of recruitment and data collection, follow-up). All participants accepted to provide feedback on the patient-education booklet and engaged in the phone interview. All assessments, data-collection procedures and enquires were conducted and managed online or via telephone.

\begin{table}
\centering
\caption{Feasibility definitions for the primary outcomes}
\begin{tabular}{|l|p{0.6\textwidth}|}
\hline
\textbf{Description} & \textbf{Feasibility definition} \\
\hline
Recruitment procedures & ► The number of individuals screened for study eligibility and consenting to participate were recorded. \\
& ► When an individual was not enrolled in the study, the reason for ineligibility or declining was recorded. \\
& ► The number of participants lost in each phase of the study was noted and the reasons for dropping out were recorded. \\
& ► To recruit a total of 20 eligible and interested individuals within 3 months of initial study advertisement. \\
\hline
Data collection & ► The number and proportion of missing data points for each questionnaire was recorded and calculated. \\
& ► The number and proportion of participants lost in each phase of the study was noted and the reasons for dropping out were recorded. \\
& ► Feedback on the data collection method, clarity of questionnaires, and length of time to complete questionnaires was gathered during the 1-month follow-up interview. \\
& ► No more than 20% missing data for secondary outcome measures and a minimum of 85% follow-up rate for enrolled participants. \\
\hline
Acceptability & ► Participants’ opinion regarding the acceptability of the intervention and their experience using the patient-education tool was investigated during the telephone interview. \\
& ► Additionally, reasons for participation in the study or for dropping out, as well as barriers and facilitators to reducing paracetamol intake in the study were explored during the 1-month follow-up interview. \\
& ► Over 50% of participants answer ‘positively’ to questions regarding acceptability on the participant feedback survey (online supplemental appendix 2). \\
\hline
\end{tabular}
\end{table}
Participants
To be included in the study, participants had to meet all of the following criteria:
1. Aged ≥18 years.
2. Be members of Musculoskeletal Australia or painaustralia.
3. Experiencing an acute, chronic, or a recurrent episode of LBP.
4. Self-reporting consumption (of any amount) of paracetamol (over the counter or prescription) for LBP (either alone or in combination with other medications) weekly for at least 1 month.
Participants were excluded if they:
1. Presented any disorder that may reduce capacity to participate in behavioural interviewing, or completion of outcome measures (eg, dementia and dysarthria).

Intervention
The intervention (education booklet) used in this study included a 12-page booklet adapted from deprescribing studies implemented by the Canadian Deprescribing Network, which have shown to be successful in medication deprescribing trials for users of NSAIDs, opioids and benzodiazepines. The textual content of the intervention was based on the work of our group as well as guidelines concerning the use of paracetamol for LBP. The theoretical framework underpinning the patient-education booklet is based on the behaviour change theory and the Capacity, Opportunity, Motivation and Behaviour model of behavioural change. The intervention was designed to change beliefs, increase knowledge and self-efficacy and create discussion with a health professional through the mechanisms of motivation, capacity and opportunity. Further details explaining the theoretical framework underpinning the patient-education booklet can be found elsewhere. Key textual concepts of the intervention include avoiding pain spiralling and catastrophising, pacing and gradual return to activity, having a peer champion, creating an activity diary, starting a discussion with a healthcare professional and engaging in safer and more effective alternatives (such as exercises, physiotherapy, mindfulness, tai chi, Pilates, manual therapy, social support groups). A link to view the patient-education booklet has been provided in online supplemental appendix 1.

Primary and secondary outcome measures
Primary outcome measures and feasibility criteria
The primary outcomes of this study were the feasibility of implementing a trial aiming to investigate the effectiveness of a patient-educational booklet to support individuals with LBP in reducing paracetamol intake. A follow-up telephone interview was used to obtain participants’ opinions regarding the intervention (booklet) and general aspects of the study (ie, ease of recruitment and data collection, follow-up). The phone interview was conducted with all study participants. The primary outcomes and feasibility criteria are outlined in table 1.

Table 2 Baseline characteristics
<table>
<thead>
<tr>
<th>Variable</th>
<th>n</th>
<th>Mean (SD) or (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>24</td>
<td>49.1 (14.8)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>8</td>
<td>33.3</td>
</tr>
<tr>
<td>Female</td>
<td>16</td>
<td>66.7</td>
</tr>
<tr>
<td>LBP symptoms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain intensity/10 (NPRS)</td>
<td>24</td>
<td>6.2 (2.2)</td>
</tr>
<tr>
<td>Duration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;6 weeks</td>
<td>8</td>
<td>33.3</td>
</tr>
<tr>
<td>6–12 weeks</td>
<td>2</td>
<td>8.3</td>
</tr>
<tr>
<td>12 weeks to 1 year</td>
<td>1</td>
<td>4.2</td>
</tr>
<tr>
<td>&gt;1 year</td>
<td>13</td>
<td>54.2</td>
</tr>
<tr>
<td>Pattern</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constant LBP</td>
<td>15</td>
<td>62.5</td>
</tr>
<tr>
<td>Episodic LBP</td>
<td>9</td>
<td>37.5</td>
</tr>
<tr>
<td>Paracetamol use for LBP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paracetamol use for low back pain was instructed by a health professional</td>
<td>14</td>
<td>58.3</td>
</tr>
<tr>
<td>Previously attempted deprescribing</td>
<td>15</td>
<td>62.5</td>
</tr>
<tr>
<td>LBP, low back pain; NPRS, Numerical Pain Rating Scale.</td>
<td></td>
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</tr>
</tbody>
</table>

Based on the results of this feasibility study, one of the following decisions were made:
1. The study is not feasible, and therefore should not proceed to full trial.
2. The study is feasible, but modifications are required.
3. The study is feasible, and no modifications are required.

Secondary outcome measures
Secondary outcome measures included the preliminary effectiveness of the patient-education booklet to educate and support patients to reduce paracetamol intake, create opportunity and increase participants’ motivation and self-efficacy to reduce paracetamol use. Clinical outcomes associated with LBP and participants’ ability to transition to safer, evidence-based approaches to manage their LBP were also collected. Deprescribing was defined as reducing or stopping medication that is no longer necessary or that may cause harm. All secondary outcomes were collected via online surveys using REDCap electronic data capture tool which was secured and hosted under the University of Sydney server. Participants who did not complete any of the secondary outcome measures received up to two automated email reminders 3 and 6 days after the due date. Participants who still did not complete secondary outcome measures were contacted via telephone after 2 weeks.

Paracetamol use
Data on paracetamol use for LBP were collected at baseline, 1-week and 1-month postintervention (online supplemental appendix 3).
Table 3 Acceptability questions (n=24)

<table>
<thead>
<tr>
<th>Questions</th>
<th>Yes (%)</th>
<th>No (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did you find the booklet a useful resource?</td>
<td>87.5</td>
<td>12.5</td>
</tr>
<tr>
<td>Did you make any changes to your paracetamol intake to manage your low back pain?</td>
<td>62.5</td>
<td>37.5</td>
</tr>
<tr>
<td>Did you make any lifestyle changes to help manage your low back pain?</td>
<td>87.5</td>
<td>12.5</td>
</tr>
<tr>
<td>Did reading the booklet prompt you to discuss your low back pain or paracetamol use with a health professional?</td>
<td>79.2</td>
<td>20.8</td>
</tr>
<tr>
<td>Would you recommend the booklet to anyone else?</td>
<td>91.6</td>
<td>8.4</td>
</tr>
<tr>
<td>If you had another episode of low back pain, would you read this booklet again?</td>
<td>91.6</td>
<td>8.4</td>
</tr>
<tr>
<td>Would you be willing to participate in a full trial?</td>
<td>91.6</td>
<td>8.4</td>
</tr>
</tbody>
</table>

Motivation
Changes in participants’ motivation to reduce paracetamol use for their LBP were assessed by comparing responses at baseline and at 1-month follow-up to the following two outcome measures:
1. Four true/false questions on the effectiveness and safety of paracetamol for LBP (online supplemental appendix 4).
2. Beliefs about Medicines Questionnaire (BMQ-Specific).24

Self-efficacy
Changes in participants’ self-efficacy to reduce paracetamol use for their LBP was assessed by comparing responses at baseline and at 1-month follow-up on the Medication Reduction Self-Efficacy Scale.25 26

Opportunity
The potential of the intervention to stimulate treatment discussions with a health professional was assessed by asking the following question at 1-week and 1-month post receiving the intervention: ‘Have you discussed or intend to discuss paracetamol use for your low back pain with a health professional after reading the patient-education booklet (intervention)?’ (Yes/No).

LBP clinical outcomes
Data on history of LBP were collected at baseline and average LBP intensity was collected at baseline and 1 month (online supplemental appendix 5).

Statistical analysis
Descriptive statistics are reported with analysis focused on estimation and variability of the data (assessed by means, SD and percentages) rather than hypothesis testing, since the study was not aimed or powered to assess statistical significance. Data from the recorded follow-up interviews of each participant were analysed quantitively and presented as proportions (%) using STATA statistical software V.15 (StataCorp. 2017. Stata Statistical Software: Release 15).

RESULTS
Study participants and follow-up
A total of 27 interested potential participants responded to the study advertisement between 1 June and 31 August 2021. Three potential participants were excluded due to not currently taking paracetamol for their LBP. The remaining 24 participants met eligibility criteria, provided informed consent and completed questionnaires at baseline, 1 week and 1 month, and the follow-up phone interview.

Baseline characteristics
The mean age of the study sample at baseline was 49 (SD 14) years, the age range was 22–70 years, and 16 (66.7%) participants were female. Thirteen participants (54.2%) had LBP duration of >1 year, eight (33.3%) had LBP duration of <6 weeks, two (8.3%) had LBP duration of 6–12 weeks and one participant (4.2%) had LBP duration of 12 weeks to 1 year. At baseline, 15 participants (62.5%) reported having constant LBP and nine (37.5%) had episodic LBP. Additionally, among the 24 participants, 14 (58.3%) had been previously instructed by a health professional to take paracetamol for their LBP and 15 (62.5%) had previously attempted to deprescribe paracetamol (table 2).

Feasibility outcomes
Recruitment procedures
All 24 participants who were eligible provided informed consent to participate in the study, resulting in a consent rate of 100%. All eligible and interested participants were successfully enrolled into the study within the timeframe of 3 months since initial study advertisement.

Data collection
There was no missing data across any of the outcomes collected at baseline, 1-week and 1-month follow-up. No participants dropped out at any stage of this study. During the phone interviews, 100% of participants reported that the electronic data collection method was ‘easy to use’, ‘there was no difficulty in understanding any of the questions’ and ‘it did not take much time to complete’. Data collection took <15 min for all participants.

Acceptability of the patient-education booklet and willingness to participate in a future RCT
Out of the 24 participants, 22 (91.6%) were willing to participate in a future trial and over 60% of participants responded positively to questions regarding acceptability of the patient-educational booklet (table 3).
Paracetamol use
At the 1-month follow-up, six (25%) participants successfully stopped, and nine (37.5%) successfully reduced their paracetamol intake compared with baseline (table 4). From the remaining nine (37.5%) participants still taking paracetamol at the 1-month follow-up, five (20.8%) did not attempt to deprescribe and four (16.7%) attempted but failed to reduce their dose. The majority of participants who successfully stopped or reduced their paracetamol intake presented with acute or subacute LBP, as opposed to chronic LBP (table 4).

Paracetamol dosage
At baseline, participants took a mean of 6.1 (SD 2.5) tablets per day (table 4). At the 1-week follow-up, they took a mean of 4.5 (SD 3.0) tablets per day, and at 1-month follow, a mean of 3.9 (SD 2.8) tablets per day. Participants with chronic LBP consistently took more paracetamol than those with acute LBP across all follow-up points (table 4).

Paracetamol frequency
At baseline, the daily average frequency of paracetamol intake for LBP among the included participants was 3.5 (SD 0.8) times per day. At the 1-week follow-up, the daily average frequency was on 2.6 (SD 1.5) times per day, while at the 1-month follow-up, the daily average frequency of paracetamol for LBP reduced to 2.5 (SD 1.6) times per day. The frequency was consistently higher for participants with chronic LBP across all follow-up points (table 4).

LBP intensity
At baseline, the average LBP intensity was 6.2 (SD 2.2), reducing to 4.5 (SD 3.0) (table 2) at the 1-week follow-up, and then to 2.7 (SD 2.2) at 1 month (table 4). LBP intensity was consistently higher in participants with chronic LBP across all follow-up points (table 4).

Motivation
Overall, more than 75% of participants increased their knowledge score (true/false questions) and their concern score, and approximately two thirds (15/24) of participants reduced the necessity score, assessed on the BMQ-Specific at 1 month compared with baseline (table 5). Participants who successfully deprescribed their intake or attempted but failed to deprescribe paracetamol consistently presented higher increases in knowledge and concern scores and reduced necessity scores, compared with those who did not attempt to deprescribe (table 5).

<table>
<thead>
<tr>
<th>Table 4</th>
<th>Low back pain (LBP) symptoms and paracetamol usage at baseline, 1 week and 1 month stratified by LBP duration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All participants</td>
</tr>
<tr>
<td></td>
<td>n</td>
</tr>
<tr>
<td>Low back pain symptoms</td>
<td></td>
</tr>
<tr>
<td>LBP Intensity at baseline</td>
<td>24</td>
</tr>
<tr>
<td>LBP Intensity at 1 month</td>
<td>24</td>
</tr>
<tr>
<td>Paracetamol dosage (500mg tablets)</td>
<td></td>
</tr>
<tr>
<td>Daily number of tablets at baseline</td>
<td>24</td>
</tr>
<tr>
<td>Daily number of tablets at 1 week</td>
<td>24</td>
</tr>
<tr>
<td>Daily number of tablets at 1 month</td>
<td>24</td>
</tr>
<tr>
<td>Paracetamol frequency</td>
<td></td>
</tr>
<tr>
<td>Daily dose frequency at baseline</td>
<td>24</td>
</tr>
<tr>
<td>Daily dose frequency at 1 week</td>
<td>24</td>
</tr>
<tr>
<td>Daily dose frequency at 1 month</td>
<td>24</td>
</tr>
<tr>
<td>Paracetamol use at baseline</td>
<td></td>
</tr>
<tr>
<td>Took paracetamol to manage low back pain</td>
<td>24</td>
</tr>
<tr>
<td>Paracetamol use at 1 week</td>
<td></td>
</tr>
<tr>
<td>Took paracetamol to manage low back pain</td>
<td>20</td>
</tr>
<tr>
<td>Did not attempt to deprescribe</td>
<td>9</td>
</tr>
<tr>
<td>Attempted but failed deprescribing</td>
<td>2</td>
</tr>
<tr>
<td>Successfully reduced their paracetamol dose</td>
<td>9</td>
</tr>
<tr>
<td>Successfully stopped their paracetamol dose</td>
<td>4</td>
</tr>
<tr>
<td>Paracetamol use at 1 month</td>
<td></td>
</tr>
<tr>
<td>Took paracetamol to manage low back pain</td>
<td>18</td>
</tr>
<tr>
<td>Did not attempt to deprescribe</td>
<td>5</td>
</tr>
<tr>
<td>Attempted but failed deprescribing</td>
<td>4</td>
</tr>
<tr>
<td>Successfully reduced their paracetamol dose</td>
<td>9</td>
</tr>
<tr>
<td>Successfully stopped their paracetamol dose</td>
<td>6</td>
</tr>
</tbody>
</table>
Building capacity
Of the 24 participants, 18 (75%) increased their self-efficacy score at 1 month compared with baseline. Participants who successfully deprescribed their paracetamol intake consistently had higher increases in self-efficacy scores compared with those who did not attempt and those who attempted to deprescribe but failed (table 5).

Creating opportunity
At the 1-month follow-up, 20 (83%) participants had discussed or intended to discuss their paracetamol intake for LBP with a health professional. Participants who attempted but failed to deprescribe and those who successfully deprescribed their intake consistently discussed or intended to discuss deprescribing with a health professional compared with those who did not attempt to deprescribe paracetamol (table 5).

DISCUSSION
The aim of this study was to investigate the feasibility of a patient-education booklet to support people with LBP to increase their motivation and self-efficacy to reduce their paracetamol intake and engage in safer and more evidence-based management strategies to manage their LBP. In particular, the study aimed to determine the acceptability of the intervention, feasibility of recruitment, data collection and willingness of participants to participate in a future RCT. The results demonstrate the study design and the patient-education booklet to be feasible for testing in an RCT, as all criteria for feasibility were met.

Summary of secondary outcomes
LBP intensity was, on average, lower across all participants between baseline and 1 month, with greater reductions observed in participants with acute or sub-acute LBP (5.3–3.8) compared with participants with chronic (6.5–5.2) LBP. Both the daily number of paracetamol tablets and daily dose frequency decreased on average among all participants at both 1-week and 1-month follow-up points compared with baseline. Greater decreases were observed in participants with acute or sub-acute LBP compared with participants with chronic LBP. Decreases in paracetamol use were more dramatic between baseline and 1 week, compared with 1 week and 1 month. In regard to deprescribing paracetamol for LBP, over half the sample had either successfully stopped their paracetamol use or reduced their dose by 1-month postintervention. A
higher percentage of the sample stopped or reduced their dose from the time between baseline to 1 week (16%), compared with the time between 1 week and 1 month (25%). The majority of participants who successfully stopped or reduced their paracetamol intake presented with acute or subacute LBP (60%), as opposed to those with chronic LBP (40%).

Comparison to existing literature

This is the first study to use a patient-education booklet to enhance motivation through increasing the knowledge of individuals with LBP about safer and more effective alternatives to paracetamol for managing LBP. However, existing research has shown improvement in knowledge scores of up to 94% of individuals with LBP after receiving more general educational interventions, as they better understand their condition and strategies for management compared with individuals in control groups.37–39 This study produced greater increases in knowledge scores among individuals who successfully deprescribed (100%), or attempted to deprescribe (100%), compared with those who did not attempt to deprescribe paracetamol (60%). These results are comparable to those of a larger study where an educational intervention to support benzodiazepine deprescribing in older adults found an 80% increase in knowledge for individuals who deprescribed, a 55% increase in knowledge for individuals with intent to deprescribe, and only 21% increase among those who did not attempt to deprescribe benzodiazepine.31

Existing literature has suggested that providing written information without an in-person education session has little to no effect on improving LBP intensity scores.32 The results of our study indicate the potential for an improvement in LBP intensity scores after providing written information, as LBP intensity reduced by approximately 50% on average across participants at 1 month compared with baseline. This difference may be due to the differing content within the interventions. Our intervention was designed to provide participants with specific skills and tools (such as an activity diary and the skill of pacing) to manage LBP, with clear examples of how to incorporate these skills in their daily activities, rather than solely providing guideline-focused messages about LBP to improve participants knowledge, as seen in previous studies.32 33 Another explanation may be through the mechanism of our patient-education booklet creating opportunity and prompting participants to discuss the management of their LBP including paracetamol deprescribing with a health professional, where they could have received verbal reinforcement of the key messages in the booklet by supportive health professionals, which has shown to increase the impact of educational interventions.32 34 35 However, these results need to be interpreted with caution given the study did not employ a randomised design and did not include a controlled intervention.

In regard to deprescribing paracetamol, no study to date has aimed to specifically deprescribe paracetamol intake in individuals with LBP. However, in 1998, a study by Cherkin et al36 found that the percentage of participants who used medication of any type for LBP decreased from 77% at baseline to 32% (p<0.05) at 1 month after receiving an educational intervention. Although, this reduction in back pain medication was greater in both the group receiving chiropractic treatment (from 82% to 18%) and the physical therapy group (from 84% to 27%). The 'Back in Action' booklet used by Cherkin et al36 presents similar content to the booklet used in our study, as they included comparable messages around activities for promoting recovery and preventing recurrences for individuals with LBP. The preliminary results from our study provide further evidence for the potential for individuals with LBP to reduce the use of paracetamol after receiving an educational intervention, as we found that 54% of participants had completely or partially reduced paracetamol for their LBP at the 1-month follow-up.

Strengths and limitations

Our study was the first study to investigate the feasibility and preliminary effectiveness of supplying a patient-education booklet for individuals with LBP taking paracetamol. A major strength of this study was the recruitment through partnership with Musculoskeletal Australia and pain Australia, which efficiently and effectively facilitated recruitment of a representative sample of individuals with LBP taking paracetamol. Another strength was that validated tools were used to assess clinical outcomes for LBP, paracetamol and changes in motivation, self-efficacy and opportunity. Data collection and outcome measure completion were very successful in this study, as there was no missing data or loss to follow-up, with a follow-up rate of 100%. However, there are a number of limitations associated with this study. We did not use a control group to compare with our intervention, which means that no causal links can be made between the intervention and our findings.37 Additionally, participants may have been highly motivated to reduce their paracetamol intake for LBP and, without a control group and blinding of treatment allocation and provision, the effects of the specific intervention on offer cannot be separated from participant characteristics or knowledge that they were participating in an intervention study. In addition, the follow-up period in this study was short (1 month), and it is unknown whether participants were successful in maintaining their reduction or cessation of paracetamol use for their LBP in the long term (ie, 1 year). Moreover, we did not collect data on other types of analgesic use and, thus, we cannot be certain that participants who successfully deprescribed paracetamol did not switch to other analgesics which may be potentially inappropriate (such as non-steroidal anti-inflammatories or opioids) instead. Also, there is potential for a natural deprescribing effect to have occurred due to the common clinical course of improvement in LBP and function for participants rather than any effect from reading the booklet. Finally, the possibility of recall bias should be considered, as data on all participant outcomes throughout the study was self-reported.38
Clinical implications and directions for future research

The patient-education booklet used in this study is low-cost, evidence-based and easy to disseminate, with enormous potential for LBP sufferers taking paracetamol. After receipt of the patient-education booklet, participants on average had improved motivation, self-efficacy, LBP intensity, facilitated discussion and reduced their paracetamol intake for their LBP.

Our findings indicate that this intervention may be impactful for increasing motivation, self-efficacy, creating opportunity to deprescribe paracetamol and improving LBP intensity in people with LBP, particularly in acute or sub-acute LBP. Existing research has indicated that people with chronic LBP find it more difficult to understand and use LBP information compared with those with acute or sub-acute LBP, which could potentially explain our findings.30 Future research should investigate the patient-education booklet used in this study in an adequately powered RCT with a long-term follow-up and additional clinical outcome measures. Alternatively, the intervention could be evaluated, integrated and scaled up to be part of existing clinical infrastructure, such as delivery before, alongside or after clinical care by a general practitioner or a physiotherapist, to enhance self-management of LBP.

CONCLUSION

The results of this study demonstrate that the patient-education booklet is feasible to implement, and both the intervention and study were well-received by participants. Receipt of the patient-education booklet was associated with increases in participant motivation, self-efficacy, the creation of opportunity for discussion with a healthcare professional, reduced LBP intensity and paracetamol intake. This study offers support for undertaking an RCT to assess the impact of the patient-education booklet on deprescribing paracetamol for LBP. The study design should include internal controls to minimise bias and consider a wider range of outcomes, including measures of health literacy, disability, usage of healthcare services and psychosocial measures.

REFERENCES


31 Martin P, Tannenbaum C. A realist evaluation of patients' decisions to deprescribe in the empower trial. BMJ Open 2017;7:e015959.


Appendices

Appendix 1.

https://tpat9766.wixsite.com/ceasenowstudy

Did you find the booklet a useful resource? (Yes/No)
Did you make any changes to your paracetamol intake to manage your low back pain? (Yes/No)
Did you make any lifestyle changes to help manage your low back pain? (Yes/No)
Did reading the booklet prompt you to discuss your low back pain or paracetamol use with a health professional? (Yes/No)
Would you recommend the booklet to anyone else? (Yes/No)
If you had another episode of low back pain, would you read this booklet again? (Yes/No)
Would you be willing to participate in a full trial? (Yes/No)

Appendix 2.

Did you find the booklet a useful resource? (Yes/No)
Did you make any changes to your paracetamol intake to manage your low back pain? (Yes/No)
Did you make any lifestyle changes to help manage your low back pain? (Yes/No)
Did reading the booklet prompt you to discuss your low back pain or paracetamol use with a health professional? (Yes/No)
Would you recommend the booklet to anyone else? (Yes/No)
If you had another episode of low back pain, would you read this booklet again? (Yes/No)
Would you be willing to participate in a full trial? (Yes/No)

Appendix 3.

At baseline participants were asked the following questions:
1. “Did you take Paracetamol this week? (Yes/No). If Yes, participants were asked questions 1.1, 1.2 and 1.3.
   1.1 “On average each day, how many tablets did you take (Dose)?”.
   1.2 “On average each day, how many times did you take paracetamol (Frequency)?”.
   1.3 “Who instructed your paracetamol intake?” (Health professional or self-initiated).

At one-week and one-month post intervention, participants were also asked the following additional questions about paracetamol use:
2. “Have you read the patient-education tool (intervention)?” (Yes/No)
3. “Have you attempted to reduce the amount of paracetamol you take to manage your low back pain?” (Yes/No). If Yes, participants will be asked question 4.1. If No, participants will be asked question 4.2.
   4.1. “Who initiated the change in paracetamol intake?” (Health professional or self-initiated)
   4.2. What was the biggest barrier to attempting to reduce your paracetamol intake?
5. “Have you swapped or attempted to swap paracetamol use for your low back pain with an alternative suggested in the patient-education tool (intervention)?” (Yes/No)

Appendix 4.

Paracetamol is an effective treatment for low back pain. (True/False)
Exercise can be effective to manage my low back pain. (True/False)
Paracetamol does not cause any side effects. (True/False)
It is safe to take paracetamol with other medications. (True/False)
Appendix 5.

1. Average low back pain intensity during the past week: 11-point numerical rating scale ranging from 0 = no pain to 10 = worst pain possible (33). N.B. Additionally, this outcome was collected at one-month post receiving the intervention.

2. How long have you experienced low back pain?
   1. Less than 6 weeks
   2. Between 6-12 weeks
   3. Between 12 weeks (3 months) to 1 year
   4. More than 1 year

3. Which of the following best describes the pattern of your lower back pain:
   1. Constant back pain (always present and never fully recovers)
   2. Recurrent back pain (periods of full recovery with no back pain, with intermittent episodes of back pain)