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Protocol

Consumer focused education on paracetamol side effects, inadequate outcomes and weaning for individuals with low back pain: protocol for a feasibility study

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ABSTRACT

Background: Prescription and over the counter medications, such as paracetamol, account for a significant proportion of the direct and indirect costs in managing low back pain (LBP). Existing research has not only questioned the efficacy of paracetamol use for musculoskeletal conditions such as LBP, but also its safety. No previous study has investigated the feasibility of a pharmacological education tool for individuals using paracetamol to manage their LBP. The aims of this study are to investigate: (1) the acceptability and experience of participants with the pharmacological education tool, (2) feasibility of recruitment, data collection and outcome measure completion, and (3) participant's willingness to participate in a randomised control trial.
Methods: This will be a single group repeated measures study design recruiting individuals from community organisations. Included participants will be over 18 years, experiencing acute, chronic or recurrent episodes of LBP and self-report consumption of paracetamol for pain relief weekly for at least one month. This study will be open for recruitment from June 2021 to August 2021.
Conclusions: Our findings will inform the feasibility of conducting a larger randomised controlled trial. This study will be judged as feasible to proceed to a full trial based if, 1) recruitment sources are each able to enrol at least 20 participants into the study within three months of initial advertisement, 2) the majority of participants find the study and intervention experience as acceptable, and 3) there is less than 20% of missing data for the primary outcomes, and a minimum of 85% follow-up rate for enrolled participants.

Keywords: Consumer, Deprescribing, Education, Low back pain, Paracetamol

INTRODUCTION

Low back pain (LBP) is one of the most disabling condition worldwide, and, as a result, it causes a significant burden on society and on the economy.[1,2] In Australia, the direct costs associated with treating LBP are approximately $5 billion per annum, with prescription and over the counter medications, such as paracetamol,

accounting for a significant proportion of this cost.[3-6] Furthermore, when additional costs are considered, such as loss of wages, disability subsidy, and decreased productivity, the economic burden almost doubles.[4]

Paracetamol has traditionally been recommended for the management of LBP.[7] However, recent studies have shown that paracetamol is no better than placebo for improving quality of life and reducing pain or disability for individuals experiencing LBP.[8-13] This led to paracetamol being removed from the list of recommended treatments for LBP in many clinical guidelines across the world, including USA, UK and many European countries.[14,15] Despite this, in Australia over 50% of individuals with LBP are prescribed paracetamol as part of their initial care.[16] This is especially concerning considering the emerging links between paracetamol and many renal, gastrointestinal and cardiovascular side effects.[17,18] Additionally, in Australia, the frequency of hospital admissions and cases of liver injury attributed to paracetamol overdose and misuse have increased by approximately 50% and 100%, respectively, since 2004.[19]

No previous study has investigated the feasibility (i.e., acceptability, willingness for behavioural change) of a pharmacological education tool for individuals using paracetamol to manage their LBP. Existing research has shown to successfully increase participants' self-efficacy and motivation to deprescribe non-steroidal anti-inflammatory drugs (NSIADs), opioids and benzodiazepines.[20,21] Additionally, it has been shown in a study by Mohammed et al that 50% of individuals using paracetamol and opioids to treat moderate to severe cancer pain were able to stop paracetamol use upon receiving advice from their health professional to cease the intake.[22] It is paramount that sustainable and effective strategies are developed and implemented to educate individuals who are under high or prolonged intake of paracetamol on limited effectiveness of this medication to manage symptoms in LBP, range of alternatives available (such as exercise, yoga, mindfulness) and risks involved with paracetamol use. Patient education on appropriate paracetamol use will increase self-efficacy of individuals with LBP to better self-manage their condition, reduce over-reliance on paracetamol, the harms this medication causes in misuse, overdoses, and the economic burden associated with its use to manage LBP.

The aims of this study are to investigate: (1) the acceptability and experience of participants with the pharmacological education tool, (2) feasibility of recruitment, data collection and outcome measure completion, and (3) participants willingness to participate in a randomised controlled trial (RCT).

METHODS

Study overview

This study will use a single group repeated measures design to determine the feasibility of a larger scale randomised controlled trial investigating a pharmacological education tool to support and educate patients with low back pain on appropriate use of paracetamol. Partnerships have been developed with two leading and large consumer groups Musculoskeletal Australia and painaustralia to recruit a total of 20 eligible participants from both these two recruitment sources and the general community for this study. The study will be advertised to the general community and to individuals subscribed to either Musculoskeletal Australia and painaustralia (online via social media and in their newsletter), with information about the study and a form to indicate participants' interest in the study. Only interested participants meeting the inclusion criteria and who provide online-signed informed consent will be included in the study. Following written informed consent, participants will then be sent an email containing a secure link to complete the baseline questionnaire. Once completed, participants will receive the pharmacological education tool via their preference (physical mail, email or web link). One week and again four weeks after receiving the pharmacological education tool, participants will be sent an email containing a secure link to complete a follow-up questionnaire, specifically, to determine if there has been any change in their paracetamol intake, and to understand participants' facilitators and barriers to change or not their paracetamol intake. Additionally, participants will be sent an email containing a secure link to complete follow-up questionnaires four weeks after receiving the pharmacological education tool. Participants will also be invited to participate in a telephone interview to investigate, in-depth, their view of the pharmacological education tool. All assessment, data-collection procedures and enquires will be conducted and managed online or via telephone. The recruitment process and study flow can be found in Figure 1.

Ethical approval

This study protocol has ethical approval, obtained from the University of Sydney Human Research Ethics Committee, reference number 2021/033.

Participants

A total of 20 participants from the partner organisations will be recruited for this study. Participants will be contacted via e-mail coordinated by each partner organisation. To be included in the study participants must meet all of the following criteria: aged >18 years, experiencing acute, chronic or recurrent episodes of LBP and self-reported consumption (of any amount) of paracetamol (either alone or in combination with other medications) for pain relief weekly for at least one month.

Participants will be excluded if they have any disorder that may reduce capacity to participate in behavioural interviewing, understand the text messages or complete outcome measures.

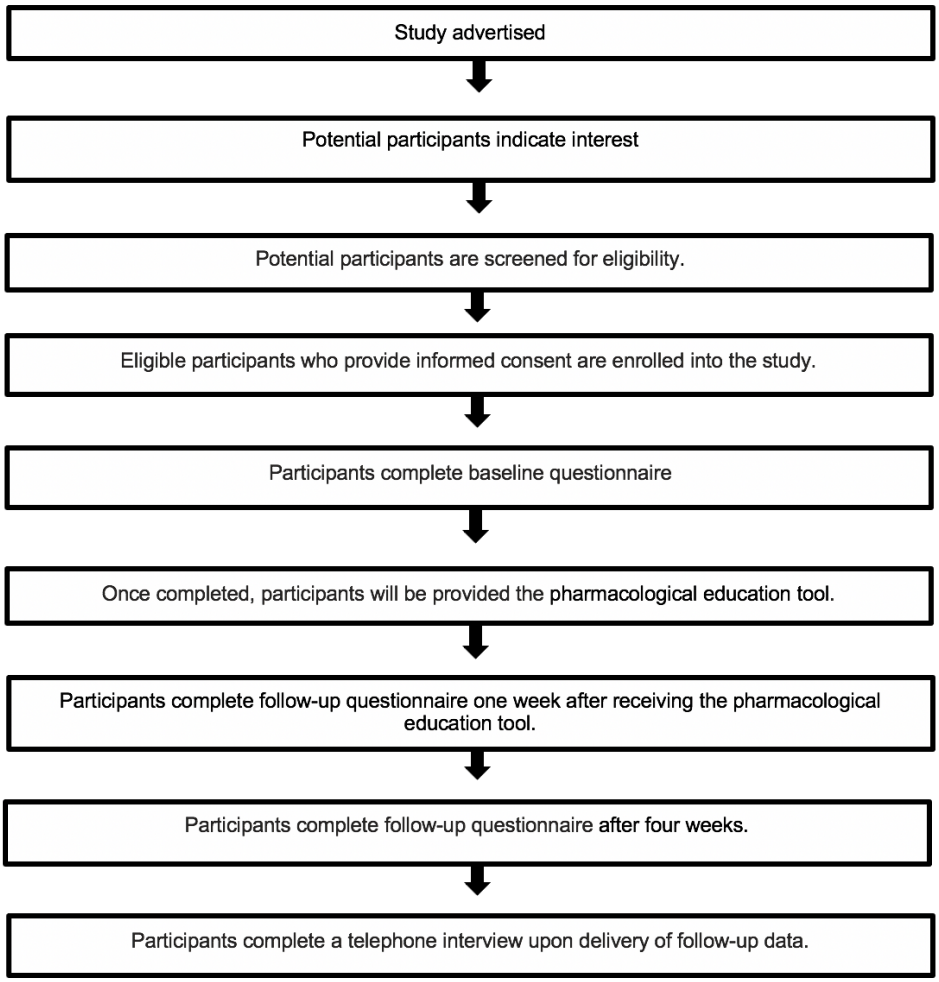

Figure 1: Study recruitment process and flow of participants.

Sample size

As the aim of this study is to investigate the feasibility of a future RCT, therefore, no sample size estimation was performed.[23,24] We have, therefore, established our sample size as 20 participants from both recruitment sources (40 in total). The results of this feasibility study will be used to generate data for sample size calculations of the future RCT. The participants selected for this feasibility study are representative of the target study population we aim to recruit for future trials (individuals registered with organisations such as musculoskeletal Australia, pain Australia and seniors' card). Additionally, if this study proves to be feasible, the same inclusion and exclusion criteria will be used in the future trial.

Intervention

Development of the intervention

The intervention (pharmacological education tool) used in this study is a twelve-page brochure adapted from similar studies implemented by the Canadian deprescribing network (CDN), which have shown to be successful in medication deprescribing trials for users of NSIADs, opioids and benzodiazepines (Appendix 1).[20,21] 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.[9,10,14]

Theory

The theoretical framework underpinning the pharmacological education tool is based on the behaviour change wheel by Michie et al specifically the COM-B model of behavioural change, targeting the mechanisms of motivation, capacity and opportunity.[25,26] Capability refers to both the psychological and physical capacity of the individual to engage in a particular activity or behaviour.[25] Opportunity is defined as the internal and external factors (including both the physical and social environment of the individual) that assist or deter a behaviour.[25] Motivation is defined as the mental processes that are responsible for decision making and directs behaviour. This includes emotional responses, impulses and habits, goals and analytical thought.[25] In this model of behaviour change, capability, opportunity, and motivation can interact in a multitude of ways to

generate behaviour, that also can, in turn, influence these mechanisms. For example, opportunity can influence both motivation and capability. Moreover, enacting a certain behaviour can alter a person's capability, motivation, and opportunity. Table 1 links the mechanisms to the corresponding components used in the Consumer-focused education on acetaminophen side effects, inadequate outcomes and weaning (CEASE NOW) pharmacological education tool (Appendix 1).

Table 1: Mechanisms embedded into the components of the CEASE NOW pharmacological education tool.

Mechanisms	Components of CEASE NOW pharmacological education tool		
Increase motivation to stop using paracetamol by changing participants' knowledge and beliefs	Messaging on the front page 'Know what you are taking' to raise awareness of the harms of paracetamol. This aims to initiate cognitive restructuring in the participants about paracetamol, LBP and the use of paracetamol to manage LBP.[26]	"Did you know" statements on 2nd page designed to challenge participants' knowledge about paracetamol, LBP and use of paracetamol to manage LBP. This builds upon the cognitive restructuring initiated from reading the front page and tries to elicit cognitive dissonance in participants by confronting them with ideas that may be inconsistent to their own pre-existing thoughts and beliefs regarding paracetamol, LBP and the use of paracetamol to manage LBP.[26]	Interactive knowledge test with 4 true/false questions and answers on the 3rd and 4th page. This aims to put the participants paracetamol consumption into question through intensifying the feelings of cognitive dissonance.[26] This is achieved by challenging their existing beliefs through convincing nature of pharmacological education tool providing information targeted at increasing their knowledge about the ineffectiveness of paracetamol for LBP, the range of alternatives available and the risks involved with paracetamol use.
Increase the capacity of participants to stop using paracetamol by augmenting self-efficacy	The sixth page of the intervention illustrates to participants the concept of graded tasks, where they begin to perform activities that are within their comfort zone, starting small and then progressively increasing the difficulty of the activity.[26] This aims to inspire individuals who might identify themselves on the downward spiral of pain and enable participants to start to reverse this spiral and get back on track.	On page 7, a list of alternative non-pharmacological approaches to manage LBP is provided to participants to use as substitutes to taking paracetamol. This instils the foundations of coping planning to participants through suggesting options to help ease the transition off paracetamol.[26] The 8th, 9th and 10th page of the intervention detail how participants can use an activity diary as a tool to self-manage their LBP. This tool builds upon the concept of graded tasks and how participants can exhibit control and take ownership in managing their LBP. Additionally, participants extend upon the foundations of coping planning through exploring relapse prevention by identifying scenarios that may result in a relapse of their behaviour to use paracetamol to manage their LBP and how this can be avoided.[26]	Social comparison theory was incorporated on the second last page through including a peer champion's narrative.[25] The narrative highlights the peer champion's previous agreement with participants views towards paracetamol use for their LBP. This is intended to reassure participants about their newfound uncertainty regarding paracetamol use through feeling comparable to a peer champion. Ultimately, the aim is for participants to identify with Ian's journey to stop using paracetamol for LBP and to feel empowered and confident to begin their own story to stop using paracetamol for their LBP.
Drive opportunities to discuss and initiate deprescribing with a healthcare provider	On the front page, logos on the intervention are used as a form of persuasive communication to provide source credibility for the consumer to initiate conversations with their health care provider.[26]	Persuasive communication is used consistently throughout the pharmacological education tool as participants are instructed in multiple sections of pharmacological education tool to talk with your doctor/health professional about other options to help manage your LBP.[26]	The printed format of the twelve-page booklet is another form of persuasive communication that makes it an effective knowledge transfer piece to take and show to a healthcare provider.[26]

Primary and secondary outcome measures

Primary outcome measures

The main outcomes of this study include aspects related to the feasibility of a trial investigating the effectiveness of the CEASE NOW pharmacological tool to support patients to reduce paracetamol consumption to manage their LBP. A telephone interview will be used to investigate participants' opinions regarding the intervention and general aspects of the study. The interview will be conducted with participants who have concluded the study and we will attempt to also interview those who have dropped out. The feasibility outcomes include:

Recruitment rate

Recruitment rate will be recorded during the entire recruitment process. Records will be kept regarding the number of individuals screened for study eligibility. When an individual is not enrolled in the study, the reason why they were ineligible for inclusion will be recorded. Similarly, if eligible, the reasons for declining participation in the study will be noted. Consent rates will also be recorded.

Data collection and outcome measure completion

The number of missing items for each questionnaire will be recorded. The number of participants completing the intervention program and answering the follow-up questionnaires will be recorded. The number of participants lost in each phase of the study will be noted and the reasons for dropping out will be recorded when possible. During the phone interview, participants will be asked about their opinion regarding the data collection method (electronic), understanding of study questionnaire and data collection tools, and length of time to complete the questionnaires.

Acceptability and experience of intervention

Participants' opinion regarding the intervention, including the relevance of the pharmacological education tool for them, will be investigated during the telephone interview. Additionally, reasons for participation in the study or for dropping out, understanding of data collection tools, participants' opinion on the data collection method, and barriers and motivators to participate in the study will be explored in the phone interview conducted after the four week follow up data collection. The data gathered from the telephone interview will be analysed quantitatively and qualitatively.

Secondary outcome measures

The secondary outcome measures in this study will investigate the preliminary effectiveness of the intervention, specifically, the potential of the intervention to reduce paracetamol intake, change participants' motivation and self-efficacy to reduce paracetamol use as well as LBP intensity rating and improve function.

Data on the potential of the intervention to reduce paracetamol intake will be collected via online surveys using REDCap electronic data capture tool, which is secured and hosted at the university of Sydney server.[27] This information will be collected at baseline, one week and four weeks post intervention. At baseline participants will be asked the following questions:

"Did you take paracetamol this week? (Yes/No). If 'Yes', participants will be asked further questions- "How much (Dose)?", "How often (Frequency)?" and Who instructed your paracetamol intake?" (Health professional, self-initiated, other).

Additional questions to be included one week and four weeks post intervention: If there is a change in Dose or Frequency of paracetamol intake after week one and/or four, "Who initiated the change in paracetamol intake?" (Health professional, self-initiated, other), "Have you read the pharmacological education tool (intervention) posted to your address"? (Yes/No) and "Have you attempted to reduce the amount of paracetamol you take to manage your LBP?" (Yes/No). If 'No', participants will be asked further question- What was the biggest barrier to attempting to reduce your paracetamol intake? "Have you discussed or intend to discuss paracetamol use for your LBP with a health professional post intervention" (Yes/No) and "Have you swapped or attempted to swap paracetamol use for your LBP with an alternative suggested in the pharmacological education tool (intervention)?" (Yes/No).

Changes in participants' motivation and self-efficacy to reduce paracetamol use for their LBP and the intensity level of their LBP will be assessed at baseline and at one month via online surveys using REDCap electronic data capture tool.[27] An email invitation with the online survey link will be sent to participants. The invitation will contain the link to collect data on the following outcomes: medication reduction self-efficacy scale.[28,29] Beliefs about medicines questionnaire (BMQ-Specific), and four true/false questions from the third page of the pharmacological education tool under "Quiz: true or false, paracetamol for LBP."[30]

Average pain intensity during the past week: 11 point numerical rating scale ranging from 0=no pain to 10=worst pain possible.[31] Patients attitudes towards deprescribing questionnaire (PATD).[32] Pain medication attitudes and questionnaire (PMAQ-14) short form.[33] Medication adherence questionnaire.[34] LBP history

survey- a) How long have you experienced LBP?- Less than 6 weeks, between 6-12 weeks, between 12 weeks (3 months) to 1 year and more than 1 year.

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), 3. Patient specific function scale.[35]

Participants who have not completed their follow-up survey will receive up to two automated email reminders at three and six days after the due date. Participants who still haven't completed their follow-up survey will be contacted via telephone 14 days after the due date.

Statistical analysis

Descriptive statistics will be used to explore the data. Analysis will focus on variability of the data (assessed by confidence intervals) rather than hypothesis testing since this study is not powered appropriately to assess statistical significance. Effects of the intervention will be represented by summary (such as mean), and precision measures (such as confidence interval). Data from the recorded follow-up interviews (Appendix 2) of each participant will be analysed quantitively and qualitatively, modelled from a similar study conducted by Martin and Tannenbaum in 2017.[36]

The phone interview will include open semi-structured interview style questions. Qualitative data from the semi-structured interview style questions will be analysed using thematic content analysis to explore the contexts under which the program mechanisms led to participants successfully stopping their paracetamol use or failing to stop their paracetamol use. Discourses will be contrasted according to whether participants discontinued paracetamol and/or expressed the intent to discuss discontinuation. Interviews will be coded using QCAmap software. Contextual themes will be derived from the data and supported by quotes. Initially, two researchers will independently read the transcripts and field notes, then collaboratively develop first order codes, which will be subsequently verified by double coding. Second order thematic coding will be performed for the purpose of building concepts.

Quantitative and qualitative results about context will be combined and analysed in an iterative fashion through use of a triangulation protocol using a convergence coding matrix. The convergence matrix will inform which contexts favourably or unfavourably influenced a participant decision to reduce or stop paracetamol based on agreement, partial agreement or dissonance between the quantitative and qualitative data. Differences will be adjudicated via discussion and consensus.

Data integrity

Study data will be collected and managed using REDCap electronic data capture tools hosted at the university of Sydney.[27] REDCap (Research electronic data capture) is a secure, web-based application designed to support data capture for research studies.[27] Data will be stored in excel spreadsheets and transferred to appropriate statistical software for analysis. Spreadsheets will be regularly scrutinized for omissions and errors.

Criteria for feasibility

Based on the results of this study, one of the following decisions will be 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.[24] The results of this feasibility study will be interpreted based on the following criteria to determine whether it is feasible to proceed to the full trial:

Recruitment rate

Recruitment will be judged as effective, efficient and feasible if we are able to successfully recruit 20 participants from each recruitment source (60 in total) within a timeframe of three months since initial advertisement of the study. If the expected number is not achieved, the reasons for declining participation will be analysed and the recruitment strategy will be restructured. Moreover, each recruitment source will be assessed on the ratio of participants screened to participants recruited as well as the time taken to recruit eligible participants for this feasibility study. Additionally, the communication material used to attract potential participants will be checked and other methods to enhance recruitment will be explored.

Feasibility of data collection and outcome measures completion

We expect no more than 20% of missing data for the primary outcomes, and a minimum of 85% follow-up rate for enrolled participants. If these targets are not achieved, the information collected during the interview regarding reasons for dropping out, participants opinions regarding the method of data collection, understanding of study questionnaire and data collection tools, and amount of time required to answer the questionnaires will be used to modify the protocol.

Acceptability and experience of intervention

We will judge the pharmacological education tool as acceptable and worthwhile if 50% or more of participants answer 'positively' to questions 3-10 of the Participant feedback survey (Appendix 2). The value of 50% for acceptability and experience of the intervention is based on results of previous studies from which the

pharmacological education tool was adapted from.[20,21] Participants' views on the intervention protocol collected during the phone interview will be used to support the interpretation of these results and to establish strategies to increase the acceptability and experience of the intervention.

DISCUSSION

There are many aspects of this study that are innovative. Firstly, this will be the first study to investigate the feasibility of a pharmacological education tool aimed at reducing paracetamol use amongst individuals with LBP. Secondly, recruiting participants through community organisations will ensure that outcomes and feedback collected will be a true representation of the general and wider community, a population that most commonly use paracetamol to manage their LBP. This will enhance the validity and generalisability of this study as well as strengthen the feasibility outcomes.

This feasibility study includes a strong rationale, thorough methodology, clear feasibility criterion and a specific plan for analysis. If this study is considered feasible in the current format, the same design and methods will be used for an appropriately powered RCT with the addition of a control group. However, if modifications are required, they will be made based on the information provided by this feasibility study, to ensure the methodological quality of the future trial. If the study is considered as not feasible, the future trial will not be conducted, saving resources that otherwise would be spent unnecessarily.

This study represents the first step towards a major advance in the field of LBP and patient education on the ineffectiveness of paracetamol for LBP management, the range of alternatives available and the risks involved with paracetamol use. The findings of this study have potential to inform future studies that aim to empower consumers to be confident in taking the first steps to manage their LBP without the need for medication, and as a result, reduce the over-reliance of using paracetamol to manage LBP. This study has the potential to, ultimately, work towards lessening the economic burden that LBP causes on individuals, communities, government and the healthcare system.

This study will investigate the feasibility of a single group repeated measures study design investigating the effectiveness of a pharmacological education tool for individuals using paracetamol to manage their LBP. Our findings will inform the feasibility of conducting a full-scale adequately powered RCT and the preliminary effectiveness of the pharmacological education tool for individuals with LBP using paracetamol.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee of the university of Sydney human research ethics committee, reference number 2021/033.

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APPENDIX

1. CEASE NOW pharmacological education tool

https://tpat9766.wixsite.com/ceasenowstudy

2. Participant feedback survey

1. What did you think of the PIS prior to enrolling in the study?
1a. What did you like or not like?
1b. Any suggestions for improvement?

2. What did you think of the PCF that you completed prior to enrolling in the study?
2a. What did you like or not like?
2b. Any suggestions for improvement?

3. Did you find the pharmacological education tool a useful resource?
3a. How was it useful?
3b. What were the most useful bits and what bits were not useful?

4. Can you describe any impacts the pharmacological education tool had on how you manage your LBP?

5. Did you make any changes to your paracetamol intake to manage your LBP?
5a. Why or why not?

6. Did you make any lifestyle changes to help manage your LBP?
6a. Why or why not?

7. Did reading the pharmacological education tool prompt you to discuss your LBP or paracetamol use with a health professional?
7a. Why or why not?
7b. If yes, how did that discussion go?

8. Would you recommend the pharmacological education tool to anyone else?
8a. Why or why not?

9. If you had another episode of back pain, would you read this pharmacological education tool again?
9a. Why or why not?

10. Would you be willing to participate in a full trial?
10a. Why or why not?