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Using a discrete choice experiment to develop a decision aid tool to inform the management of persistent pain in pharmacy: a protocol for a randomised feasibility study

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ABSTRACT

Introduction In an era of personalised healthcare, it has become increasingly important to elicit individual-level preferences. While discrete choice experiments (DCEs) are widely used to measure patient preferences in the delivery of healthcare, the focus has been sample-level analysis. Using the DCE methodology, this project has designed a digital decision aid tool (DAT) with the potential to estimate individual preferences in real time to inform clinical consultation decisions in persistent pain management.

Methods Using a feasibility randomised control trial, this study aims to assess the feasibility of using this Understanding Persistent Pain (UPP) DAT in a pharmacy-based clinical setting and to test processes for a future definite randomised trial. Community and practice-based pharmacists (up to 10) will be recruited in The National Health Service (NHS) Grampian and trained in the use of the digital UPP DAT. Pharmacists will recruit up to 60 patients who are living with persistent pain. Patients will be randomised to one of two groups: using the UPP DAT or usual care. Pharmacists will follow-up patients as needed according to clinical need and following standard practice. DCE response data collected by the UPP DAT will be analysed using the penalised logit model, allowing estimation of individual preferences in real time. We will follow-up pharmacists and patients who use the UPP DAT to gather feedback on their experiences.

Ethics and dissemination This study received ethical approval from the North of Scotland Research Ethics Committee (21/NS/0059) and received Research & Development Management Permission to proceed from NHS Grampian (2021UA003E). The study has been registered in the ClinicalTrials.gov database. Findings will be disseminated in peer-reviewed publications, presentations and newsletters and made available in the University of Aberdeen and Pharmacy Research UK websites. Participants gave informed consent to participate in the study before taking part.

Trial registration number NCT05102578; clinicaltrials.gov.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ We use the discrete choice experiment methodology to develop a decision aid tool (DAT) capable of estimating individual preferences in real time.
⇒ Our Understanding Persistent Pain (UPP) DAT generates a personalised report to help inform treatment choices.
⇒ Development of UPP DAT was informed using extensive patient and relevant stakeholders' input.
⇒ It is not feasible to incorporate all features that may affect patient's pain management preferences in the DAT.
⇒ The study will be undertaken in The National Health Service (NHS) Grampian in Scotland and may not be generalisable to other regions or primary care areas.

INTRODUCTION

Decision aid tools (DAT) can facilitate shared decision-making and help deliver patient-centred care.[1] DATs are resources designed to help people make informed choices about healthcare that consider their personal values and preferences.[2] Studies have found that DATs can improve patients' knowledge and make them feel better informed about their preferences and values.[3 4] Furthermore, DATs can improve health literacy concerning the underlying condition, resulting in more efficient interventions.[5] Many DATs have been developed, varying in format (eg, leaflet, video or online website), type of information presented (eg, clinical problem, outcome probabilities), methods used to clarify patients' values (eg, ranging from simple information to exercises to help them clarify what matters most to them) and degree of participation in decision-making. A fundamental drawback of most existing DATs is that they fail to explicitly ask patients to consider trade-offs between the treatment characteristics, deviating from how patients normally and intuitively make decisions in real life.[6 7]

Discrete choice experiments (DCEs) are a widely used method to elicit preferences in healthcare delivery.[8–10] DCEs are rooted in economic theory, thus providing an analytical framework that can incorporate multiple and competing criteria in a way that mimics real-life decision-making processes.[11] DCEs assume that services (or goods) can be described by a set of characteristics or features, which vary systematically to form alternative packages. Individuals are asked to compare and choose between competing alternatives, thus implicitly trading off the features of each, in several choice tasks. Through the individuals' repeated choices, it is possible to estimate the relative importance of each feature and obtain quantifiable measures of preferences.[12] In other words, it is possible to work out what features are liked and disliked, and by how much relative to each other.

While DCEs offer a salient mechanism to intuitively estimate the trade-offs and relative importance of different treatments' features (eg, benefits, risks), to our knowledge, there are only two studies using this approach within a DAT framework. Dowsey et al[13] used a DCE as part of a decision aid for patients undergoing total knee arthroplasty. They conducted a randomised control trial (RCT) to determine whether completing a DCE prior to surgery influenced patient expectations, health outcomes and satisfaction. They focus on the value of the completion process of the DCE to inform the patient. Hazlewood et al[14] evaluated a proof-of-concept DAT for patients with early rheumatoid arthritis, which included a DCE to assist respondents in making a choice of initial treatment. DAT responses were combined with data from a previous DCE study to infer the patient's preferred treatment.

In this study, we use the DCE methodology to develop a DAT that directly estimates preferences at the individual level in real time without relying on a previous data set. Our application is in persistent pain, estimated to affect 28 million adults living in the UK and which has been highlighted as a national priority.[15] The digital Understanding Persistent Pain (UPP) DAT uses the patient DCE responses to create a personalised report that interprets the trade-offs and relative importance of different features of persistent pain management strategies. Pain is a subjective experience and highly preference sensitive.[16] Research has shown that patients with persistent pain value personalisation of care.[17] Furthermore, there is substantial preference heterogeneity in patients' choices for support for persistent pain management .[18] This is unsurprising since individuals will have different experiences, health needs, expectations and treatment preferences. In clinical and research practice, pain intervention approaches (pharmaco-driven and non-pharmaco-driven) tend to focus on average pain intensity.[19] However, this may not be the most important outcome to patients. As such, the management of persistent pain should take a patient or person-centred approach and involve shared decision-making.[20–22]

At the same time, there is growing evidence that patients would benefit from pain management strategies that actively involve pharmacists.[23–26] This paper describes a research protocol to investigate the feasibility of using the digital UPP DAT as part of a pharmacy-led pain consultation. There is, however, a lot of variation in existing pharmacist-led pain consultations and scarce guidance on how to ensure that these can lead to shared decision-making and patient-centred care.[27–30] This feasibility RCT will assess the feasibility of using the UPP DAT in a pharmacy-based clinical setting and to test processes for a future definite RCT.

METHODS

The primary aim of the study is to examine the feasibility of using the digital UPP DAT in clinical consultations between pharmacists and adults with persistent pain. We will also inform future parameters for a future RCT and assess the feasibility of the collection of secondary outcomes. The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines, adapted for feasibility studies, were used to guide the preparation of this protocol.[31 32] Table 1 summarises SPIRIT applied to our protocol; in what follows we provide more detail. The trial methods are also summarised in the WHO Trial Registration Data Set (online supplemental material table A1). The study procedures for prescribing and non-prescribing pharmacists are outlined in online supplemental material figure A1,A2.

Study design

The design is an RCT, unblinded, with two parallel groups and a simple randomisation until target recruitment or the study end date (whichever happens first). A 2:1 (intervention:control) allocation ratio will be applied to test the UPP DAT with more patients.

The intervention group will be asked to take part in a pain consultation using the digital UPP DAT and the control group in a pain consultation following usual care (ie, without a digital DAT.) The study is set in the NHS Grampian region (Aberdeen and Aberdeenshire, Scotland). The consultation can either take place face-to-face or remotely (eg, using the NHS *Near Me* platform).[33 34] The remote option is included considering the ongoing COVID-19 pandemic and potential restrictions to face-to-face interactions and to account for any postpandemic rise in remote consultations in health services.[35 36] For face-to-face consultations, the UPP DAT will be completed using any internet-enabled device in the consultation room. For *Near Me* consultations, the UPP DAT will be completed using an on-site computer, with the pharmacist sharing the screen with the patient.

Pharmacist recruitment

Registered pharmacists, based in a community pharmacy or General Practitioner (GP)-practice, with or without an independent pharmacist prescribing qualification, with an interest and/or experience of managing persistent pain in NHS Grampian, are eligible to take

Table 1 Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) for enrolment, interventions and assessments

	Study period				
	Enrolment	Allocation	Post-allocation		Close-out
Timepoint	*0*	*0*	*t₁ – Pain consultation*	*t₂ – follow-up*	*T₃ – debrief*
Enrolment					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
Interventions					
Control group: no decision aid tool.			◄━━━━━━━━━━━━►		
Intervention group: using decision aid tool.			◄━━━━━━━━━━━━━━━━━►		
Assessments					
Decision Conflict Scale			X		
EQ-5D			X	X	
Chronic Pain Grade			X	X	
Personal Wellbeing Scale			X	X	
Qualitative data interview					X

EQ-5D, EuroQol five dimensions questionnaire.

part. Expressions of interest will be sought following an email to all general practices in NHS Grampian, sent by the NHS Research Scotland Primary Care (NRS Primary Care) network, social media alerts from the Royal Pharmaceutical Society in Scotland and the NHS Grampian Pharmaceutical Care Services. All participating pharmacists will receive training, including a Good Clinical/Research Practice course, enrolment in a Continuing Professional Development eligible course in Musculoskeletal and Chronic Pain,[37] a webinar session with a pain consultant (highlighting biopsychosocial approaches to pain management, covering self-management and pharmacological management of pain in depth) and a session on the study procedures and UPP DAT use provided by the research team.

Patient recruitment and consent

Pharmacist will identify patients to take part in the study from personal knowledge and opportunistically as they present. Inclusion and exclusion criteria are defined below:

Patient inclusion criteria
► Above 18 years old.
► Suffering from non-malignant persistent pain (defined as pain lasting more than 3 months).
► Being managed entirely within a primary care setting.

Patient exclusion criteria:
► Not fluent in English.
► Have concomitant severe mental health problems or terminal illness.

► Suffer from pain caused by cancer or other malignancy
► Are not able to give informed consent (eg, because of mental state).
► Taking part in another research study.

Pharmacists will take informed consent from patients. For face-to-face consultations, the patient will complete and sign a consent form (see online supplemental material). For remote consultations, the pharmacists will complete and record a verbal consent form.

Sample size

We will recruit 10 pharmacists and 60 patients. Sample sizes are based on available funding, resources (eg, pharmacist time to deliver the UPP DAT) and study duration and pilot study norms.

Randomisation

Pharmacists will randomise to intervention or control at patient level using a study-specific online randomiser, designed by the research team and hosted by the software company Qualtrics, after informed consent has been given and before the pain consultation.

The intervention—DAT

The intervention is the use of the digital UPP DAT. This tool follows the principles of the National Institute for Health and Care Excellence decision aids process guide.[38] The DAT's wrapper application is coded and hosted by the company *Clinvivo*.

Table 2 Attributes and features used in the DCE choices

Attribute	Levels	
Actions they need to take		
Use over-the-counter medicine	Yes	No
Use prescription medicine	Yes	No
Follow an exercise plan	Yes	No
Receive extra coping strategies	Yes	No
Expected outcomes		
Feeling on an average day	Better (less discomfort)	As it is now
Number of bad days	Fewer days	As it is now
Ability to do activities	Better (more activities)	As it is now
Side effects	Likely	Unlikely
DCE, discrete choice experiment.		

The UPP DAT has three main sections. The first section asks people about their current pain levels, current management plans and impacts on their life and aims to establish a structured clinical pain history spanning biological, psychological and social domains.

The second section includes the DCE component with a series of questions that ask users to choose between different pain management plans. The plans are described by features and corresponding levels, which include broad categories of guideline-based pain management strategies routinely available in clinical practice.[39] The feature descriptors and their format were informed by a systematic literature review[40] and qualitative research study that involved semistructured interviews with 9 GPs, 10 pharmacists and 24 patients living with persistent pain from across Grampian.[41] Following this, the eight features described in table 2 were identified as important and relevant to patients living with persistent pain. These relate to both the actions they need to take and the expected outcomes.

We used experimental design methods to identify a manageable set of choices to present to individuals.[42 43] This design combines the attributes and levels into management plans that differ systematically across

Figure 1 .Example choice from the Understanding Persistent Pain Decision Aid Tool (UPP DAT).

Figure 2 . Example of personalised report from the Understanding Persistent Pain Decision Aid Tool (UPP DAT).

the choice tasks, aiming to present realistic combinations that maximise the precision of the parameter estimate for the main effect of each feature when analysed using a penalised logit regression model that can be analysed in real time (see below).[44] The experimental design resulted in 12 choices, each offering a choice between two hypothetical pain management plans. Figure 1 shows an example choice set.

We will ask patients to take a fresh look at their pain management and choose between the different management plans, described by the actions they need to take and expected outcomes on their life. When patients make these types of choices, they implicitly trade off the different attributes described in table 2, which allows the estimation of quantifiable measures of preference for each feature using econometric models.[45]

The third section is a personalised report, which includes the patient's answers to the first section's questions and the results of the analysis of the DCE responses showing the features of a management plan they like and/or how important they are to them. As shown in figure 2, the report will display the order of importance of the different features and visually illustrate the magnitudes of each in terms of the others (eg, how much a feature is liked or disliked with respect to the others). The UPP DAT will then prompt the patient to discuss the preference report with the pharmacist in a shared decision-making context, so that it can inform that discussion and ultimately the management plan. Pharmacists and patients will be able to review the raw data (eg, responses to the questions). In case the statistical model fails to converge, or the participant withdraws in the middle of the consultation, the report will instead display a summary of the responses to the previous questions. The UPP DAT will not make a medical recommendation.

Agreed management plans will be based on strategies routinely available in local clinical practice and will depend on the prescribing qualifications of the

pharmacist. Where a prescription medicine is deemed beneficial, pharmacists who are qualified independent prescribers will authorise this directly. Pharmacists without this qualification will, with the patient's agreement, book an appointment with the GP and send a letter to the GP with their recommendation for a prescribed medicine. Adherence to the consultation outcome and management plan will be up to the patient. Pharmacists can arrange a follow-up consultation according to clinical need and if deemed beneficial to the patient.

The UPP DAT has been pretested to check ease of comprehension of its content and presentation. This involved feedback sessions with local patient groups and members of the study's Patient Advisory Group (PAG), consultations with healthcare professionals (pharmacists, GPs and specialised pain consultants) and opportunistic think-aloud sessions carried out by the research team with colleagues. This stage identified issues concerning the DCE choice tasks and difficulty understanding the results. We made changes to the design, going from three-alternative to two-alternative tasks, to make the choice questions more intuitive and easier to complete. We also edited the personalised report format, which previously used positive–negative bar and pie charts to present results, to one which lists the relative ranking and illustrates using a normalised bar chart the relative magnitude of the parameter estimates, grouped by actions and outcomes. Furthermore, after a suggestion from healthcare professionals, we added extra clinical screening questions that could help guide the consultation. We also made changes to wording and rearranged content to make instructions clearer and easier to understand. The UPP DAT was also stress tested to verify its stability and reliability across different devices (eg, ensuring the tool can serve responses to the expected user count).

Control
The control group will undertake the consultation without the use of the digital UPP DAT.

Study outcome measures
Primary outcome measures are related to:
► Technical performance of the UPP DAT—does the UPP DAT generate individual-level preference estimates, does the model converge, is an individual report produced, face validity of parameter estimates.
► Pharmacist views about potential usefulness in the clinical setting. All pharmacists will be invited to a telephone debrief interview to explore their experience of taking part in the study, using the UPP DAT in their clinical setting and the pain consultations in general. The interview will be audio recorded and fully transcribed.
► Patient participants allocated to the intervention group will be invited to a debrief telephone interview with a member of research team to explore their experience of using the UPP DAT. The interview will be audio recorded and fully transcribed.

To inform a future RCT, we will also assess: (1) feasibility of recruitment processes, (2) response and retention rates and (3) timeline and resources required to collect and analyse data. Data on recruitment and consultation details will be recorded by the pharmacists in a patient activity log.

Secondary outcome measures are related to the feasibility of collecting the following outcome measures collated into a paper or electronic survey form to be completed immediately following the pain consultation and after 4 to 6 weeks.
► *Personal Well-Being Scale*: developed by the Office for National Statistics, it contains questions measuring four domains of well-being, namely, life satisfaction, worthiness, happiness and anxiety.[46]
► *EuroQol five dimensions questionnaire (EQ-5D):* an instrument that measures health outcomes on five dimensions, namely, mobility, self-care, usual activities, pain/discomfort and anxiety/depression.[47]
► *Chronic Pain Grade (CPG)*: a 7-item scale, which assesses pain severity on two domains (disability and intensity). The CPG scale classifies pain according to level of intensity and disability ranging from I (low disability-low intensity) to IV (high disability-severely limiting).[48]
► *Decisional Conflict Scale*: a validated instrument to evaluate patients' decision-making processes and satisfaction with their choice, aiming to assess the interactions using the UPP DAT and the overall shared decision-making process[49] (only included in postconsultation survey).

Pharmacists will ask patients to complete the survey at the end of their pain consultation. Patients will be followed up by the research team by post and asked to complete the survey again, online or by post (see table 1).

Patient and public involvement
The UPP study has a patient representative as part of the research team who has contributed to the study aim, design, methods and dissemination plan. The study also has a PAG who meet regularly to provide feedback on findings from the study's preliminary stages and help inform this study design. The UPP DAT's DCE component was informed from a qualitative stage that actively involved patients in NHS Grampian. Patients involved in this stage were provided a summary of the results and given the opportunity to provide feedback to ensure the findings matched their experience. The UPP DAT was presented to local patient groups to obtain feedback on its usability and content as part of its design stage. PAG members used the UPP DAT in a mock consultation with a GP with expertise in pain management (member of the research team) and provided feedback that helped design and edit its content and format. Findings and dissemination plans will be discussed and agreed with the PAG.

Data analysis

DCE responses will be modelled under the Random Utility Maximisation framework[50], using variants of the multinomial logit (MNL) model. This framework assumes respondents make choices described by:

$$U_{ntj} = V_{ntj} + \varepsilon_{ntj} \text{ (Eq} \tag{1}$$

where participant (n) at choice task (t) selects the alternative (j) yielding the highest level of utility (U_{ntj}). The utility is divided into an observed deterministic component (V_{ntj}), which is described by the preferences for the features' levels and an unobserved random component (ε_{ntj}). The deterministic component is an addition function of the features and their respective parameter estimates, such that:

$$V_{njt} = \sum_k \beta_k X_{kjt} \text{ (Eq} \tag{2}$$

where β are the parameter estimates for marginal changes in the levels (X) for the features (k) described in table 2. The errors assumed to be independently and identically distributed (*iid*) as type 1 extreme values, leading to the MNL model. A limitation of this model to describe individual-level preferences is that it often does not work in small samples, such that it may require more observations (eg, choice tasks) than it is feasible to present to the respondent.

We overcome this small sample limitation by using a penalised MNL (pMNL) model. First proposed by Firth[51] and introduced to DCEs by Kessels *et al*[52], this model uses a bias term in the standard likelihood function to obtain a penalised likelihood function, such that:

$$L^* \left(\beta \right) = L \left(\beta \right) \det \left(I \left(\beta \right) \right)^{\frac{1}{2}}, \text{ (Eq} \tag{3}$$

where $L \left(\beta \right)$ is the likelihood and $I \left(\beta \right)$ is the Fisher Information matrix. This penalisation aims to decrease estimation bias and help stabilise the model when small sample bias is likely to occur. Crucially, it allows to estimate parameters from a manageable number of choice tasks without relying in prior samples. Thus, using a pMNL allows us to estimate preference parameters for each feature at the individual level in real time, which can be used to inform a personalised report. As well as assessing if the model converges to estimate parameters, consideration will be given to the face validity of estimated parameters.

Transcription of debriefing interviews with pharmacists and patients will be overseen by the research team. Analysis will begin as soon as data collection begins and involve an iterative process beginning with independent reading and immersion in the data followed by identification of recurring themes, coding and categorising of the data. The themes and subthemes identified from the interview data will be organised and analysed using the Framework approach.[53] To ensure the validity of the analysis, two or more research team members will code and extract data from a random subset of interview transcripts independently. Emerging coding frameworks will

be compared, and any disagreements resolved through team discussion.

Data on the length and type of consultation (eg, face-to-face vs remote), recruitment and retention rates and response rates to outcome questionnaires will be recorded at the pharmacist level using a patient and activity log. The effectiveness of the digital UPP DAT on secondary outcomes will not be assessed.

Data management

Data management and monitoring will follow the Sponsor's (University of Aberdeen) Standard Operation Procedures, Health Research Agency Research Governance Guidance and the NHS Code of Practice on Protecting Patient Confidentiality.

ETHICS AND DISSEMINATION

This study has undergone internal and external peer review as part of the funding process. This study received ethical approval from the North of Scotland Research Ethics Committee (21/NS/0059) on 1 June 2021 and received Research & Development Management Permission to proceed from NHS Grampian (2021UA003E) on 3 June 2021. The study was registered in the ClinicalTrials.gov database on 1 November 2022. The study findings will be used for publication in academic journals and presentation at scientific meetings. Participating pharmacists will be sent a summary of the study key findings. A lay summary of findings will be made available at the Health Economics Research Unit (http://www.abdn.ac.uk/heru) and other University of Aberdeen websites. A technical report will be prepared for Pharmacy Research UK, which will be available in their website. The PAG will be consulted on dissemination decisions.

Study status

Recruitment of pharmacists began in January 2022 and of patients in May 2022 and is expected to continue until September 2022.

collection, management, analysis or interpretation of the data and will have no input to the writing of the report or decision to submit for publication.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Consent obtained directly from patient(s)

Provenance and peer review Not commissioned; peer reviewed for ethical and funding approval prior to submission.

Data availability statement No data available.

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