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## The DECISION project: DiscrEte Choice experIment Spinal manipulative therapy for lOw back paiN: A study protocol <sup>☆</sup>



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### ABSTRACT

The smallest worthwhile effect (SWE) is the smallest beneficial effect of an intervention that justifies the costs, risks, and inconveniences. The objective is to establish the SWE of spinal manipulative therapy (SMT) for the treatment of low back pain (LBP), and to gain insight into how different attributes of the treatment are traded among each other when choosing SMT. Part 1. A mixed-methods study will be conducted to establish and prioritize a list of attributes influencing choices for those who consider SMT for the treatment of LBP. Individual interviews and consensus groups with chiropractors, manual therapists, and osteopaths and their patients will be conducted. Interviews and consensus groups will be voice-recorded and transcribed verbatim. Part 2. A Discrete Choice Experiment (DCE) will be conducted among people with LBP who have limited to no experience with SMT. Participants will be recruited through an online independent panel company. The survey will consist of several choice sets with attributes and their levels established from Part 1. The DCE will be preceded by a short survey to understand the clinical aspects (i.e. presentation, history and previous treatment for LBP) as well as socio-demographic characteristics of the participants.

<sup>☆</sup> **Related research article:** None.

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## Specifications table

Subject area	Medicine and Dentistry
More specific subject area:	<i>Manual Therapy, Spinal Manipulative Therapy, Low back treatment, Conservative treatment</i>
Name of your protocol:	The DECISION project: DiscREte Choice experiment Spinal manipulative therapy for lOw back paiN: a Study Protocol
Reagents/tools:	<i>Not applicable</i>
Experimental design:	<i>Part 1: establishing attributes by conducting interviews and consensus groups with practitioners of SMT and patients. Part 2: conducting a DCE to determine the SWE of SMT for LBP. The DCE will consist of questions on sociodemographic information and information on the extend of the LBP, followed by the choice tasks of the DCE. The choice tasks will ask the participants to make a decision between two possible treatments for their LBP, differing from eachother in the attributes established in part 1. With specific software the data will be analyzed to establish the SWE and to establish to what degree the different attribute influence the SWE.</i>
Trial registration:	<i>Not applicable</i>
Ethics:	Written informed consent will be obtained from all participants before taking part in both the qualitative study as the DCE. Data will be safely stored and archived on YODA.
Value of the Protocol:	<ul style="list-style-type: none"> <li>The primary objective is to determine the SWE. The SWE is the smallest beneficial effect of an intervention that justifies the costs, risks and inconveniences.</li> <li>The secondary objective of this study is to establish how much importance patients assign to various factors that may affect care seeking behavior for SMT for LBP sufferers. These objectives will assist in the interpretation of the clinical relevance of the intervention of SMT. The SWE is superior to the already existing thresholds as these are not intervention-specific and are not from the patient's point of view.</li> </ul>

## Background

Low back pain (LBP) is a common problem and a costly burden to society [1–3]. Low back pain guidelines recommend several treatment options, one of which is spinal manipulative therapy (SMT) [4–7]. SMT has previously been described as a hands-on therapy directed towards the spine, which includes both manipulation and mobilization, typically performed by chiropractors, manual therapists and osteopaths [8,9]. This study will be conducted in the Netherlands, a country with a population of over 17 million. Currently, there are 507 chiropractors [10], 1503 manual therapists [11], and 844 osteopaths [12] actively practicing in the Netherlands.

In order to assess whether an intervention is effective, two aspects of clinical trial results are typically assessed: 1) statistical significance and 2) clinical relevance. The former is traditionally evaluated according to its P-value (or confidence interval), although there is increasing movement from the international scientific community against its use [13,14]. The second aspect, clinical relevance, assesses the importance to different stakeholders, among which the patients [15]. The effectiveness of an intervention can be determined more accurately by having knowledge about the clinical relevance of a specific intervention, relative to an alternative. Accordingly, treatments can be tailored more to the wishes and needs of the patients. Consequently, it is important to establish the clinical relevance of an intervention from the perspective of the patient rather than from the perspective of the researcher, clinician, or policymaker, as these have been traditionally determined in the past. The opinions of patients regarding the size of an effect of an intervention must be determined, relative to an alternative, considering costs, risks and inconveniences. Currently, these values are not widely established. Therefore, it is important not to accept a generic value when evaluating effectiveness [16].

One way to express the clinical relevance is the smallest worthwhile effect (SWE), which is the smallest beneficial effect of an intervention, relative to an alternative (expressed as between-group differences), that justifies the costs, risks, and inconveniences of that intervention [17]. Three criteria to effectively establish the SWE are: 1) it is evaluated from the patient's perspective; 2) it is intervention specific; and 3) it is expressed in the between-group difference to a control group, rather than in changes over time (within-group difference) [17]. The SWE was deliberately chosen above terms such as 'minimal clinically important difference', 'minimum important reductions', 'minimum important difference' or 'minimally important change', because they are often used interchangeably and confusing. Therefore this paper uses the between-group difference and emphasizes which alternative therapy it is compared to.

One method to establish the SWE that complies with all these criteria is the discrete choice experiment (DCE). The DCE is a method originating in economic sciences, but also fits choices that patients are confronted with in healthcare [18–20]. In a DCE, participants are asked to make choices between minimally two scenarios that describe similar features (attributes) of treatment, with attributes differing in their levels (i.e. the choices). In the DCE, the choices made by participants are used to evaluate which costs, risks, and inconveniences patients are willing to trade for the size of treatment effect [21]. Therefore, DCEs have been used frequently for healthcare-related issues in the past decades [18–20].

The SWE has been established for various treatments for LBP. Previous studies have demonstrated that LBP patients want 30% more pain reduction from NSAIDs than from no intervention [22,23]. Other studies that investigated the effect of the SWE for LBP patients who underwent an exercise program suggested a 20% reduction in pain compared to no intervention [22–24]. Regarding exercise programs for LBP, it appears that patients prefer brief, low-cost, home-based exercises, while the effective exercise programs have a longer duration and higher frequency. Another study demonstrated that participants over the age of 50 preferred not to do exercises at all [25]. Additionally, surgery is preferred over non-surgical interventions for LBP if the symptoms are severe and persistent [26]. Importantly, these aforementioned studies determined the SWE by conducting less elaborate methods, such as the benefit-harm trade-off. In a benefit-harm trade-off, the choice offered to participants differed in only one attribute: the effect size of the treatment. In contrast, the DCE provides information on how other attributes influence the SWE, and not just limited to one

attribute. Most importantly, the SWE has not yet been established for the treatment of LBP with SMT, it is expected that patients' considerations when choosing for SMT will differ from those who choose for other interventions for the treatment of LBP.

The objective is to establish the SWE of SMT for the treatment of LBP compared to no treatment, and to investigate how different attributes of the treatment are traded among each other.

## Description of protocol

This mixed-methods study will consist of two major parts: Part 1) a qualitative study and Part 2) a DCE. The qualitative study will allow us to establish the attributes and its levels, which are needed for the second part of the study. In the DCE, the SWE and the relative importance (weight) of these attributes regarding the choice for SMT in the treatment of LBP will be investigated (Fig. 1).

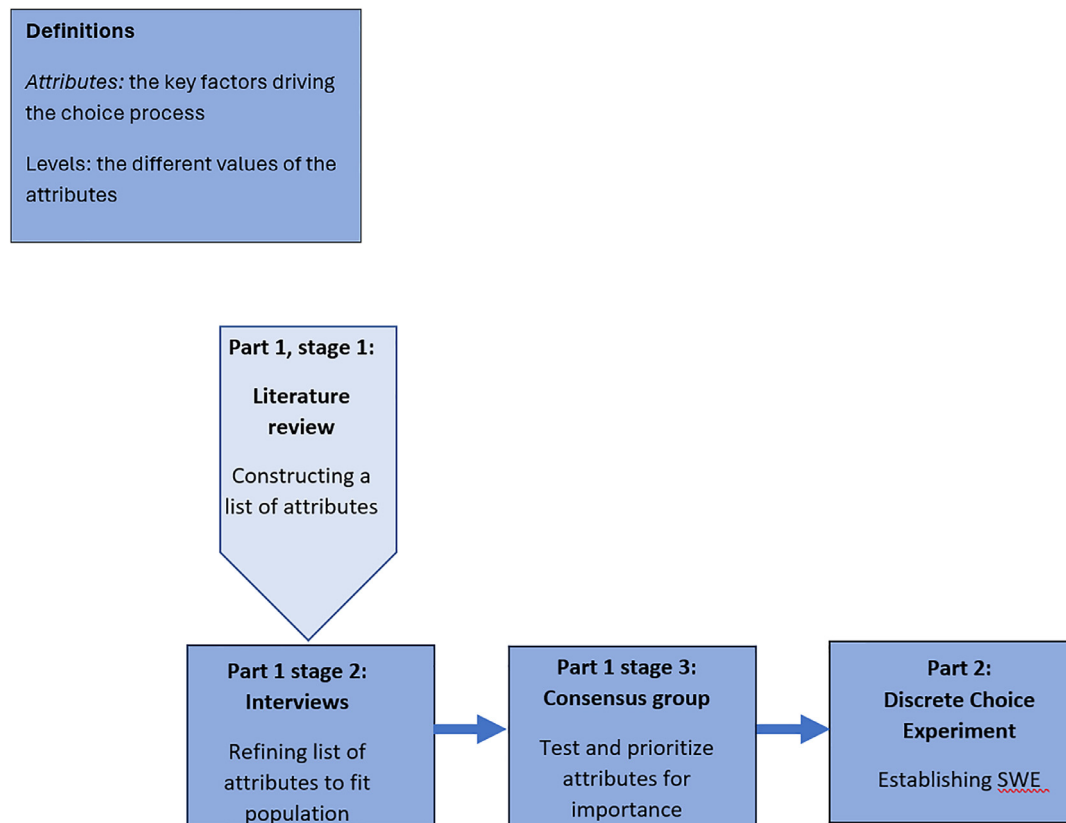


Fig. 1. Workflow diagram.

## Part 1 - Qualitative study

The aim is to identify a list of attributes necessary to be able to design the DCE. Part 1 will consist of three stages: Stage 1) A literature review to construct a longlist of attributes, which will be used to inform the topic guides for the interviews; Stage 2) Individual interviews with health care providers (chiropractors, manual therapists, and osteopaths) and patients who have been treated by one of these providers to establish the attributes relevant to this population; and Stage 3) Consensus groups with the aforementioned practitioners and patients in order to test and prioritize which attributes identified in the first and second stage are most applicable for the DCE.

### Stage 1: the literature review

In 2021, a systematic review was published in which the attributes underlying the choice for non-surgical treatment for LBP were investigated [27]. This review included papers up to June 2018.

We will conduct an update of this review to include papers published after June 2018. The same search strategy used in the systematic review will be repeated. The results from 2018 onwards will be searched for any additional attributes. The attributes identified in the original review along with the potential attributes found during the search update will inform the topic guides for the interviews in stage 2.

## Stage 2: the interviews

### Design

We will construct an explorative, qualitative study using semi-structured interviews. This study will be an interpretative study to understand the considerations and preferences of patients with LBP when choosing for a treatment with SMT. This approach allows us to explore and understand the complexity of the considerations before choosing treatment for LBP, providing us with profound insights into the attributes influencing LBP patients choosing SMT treatment in the Dutch setting.

### Sampling

A purposive sampling strategy will be used to ensure a balanced division between the different professionals and patients, with roughly one professional for every 3 patients. It is expected that a total of 12 to 15 interviews divided across the various professional groups will be necessary in order to reach data saturation [28–30].

Health care providers and patients will be contacted through the network of the project team and/or the respective national associations and their members (Nederlandse Chiropractie Associatie (NCA), MSG Science Network Physiotherapy and Nederlandse Vereniging voor Osteopathie (NVO)). We will recruit members of a national association to ensure the practitioners have received legitimate education, since both ‘chiropractor’ and ‘osteopath’ are not protected titles in the Netherlands. Potential participants will be contacted by e-mail or telephone by the interviewer to ensure they fulfill the inclusion criteria and to schedule an appointment for the interview. Information will be sent to the participant by e-mail. Written and verbal informed consent will be obtained prior to the conduct of the interview. The participants will be given the opportunity to ask questions at the beginning and at the end of the interview, and will be told that they can withdraw from the interview at any time. The participants will be interviewed once, and the interviews are expected to last one hour.

### Inclusion- and exclusion criteria

#### Patients

*Inclusion criteria:* LBP patients over the age of 18, currently being treated with SMT by a chiropractor, manual therapist, or osteopath.

*Exclusion criteria:* Not mastering the Dutch language

#### Health care providers

*Inclusion criteria:* Chiropractors, manual therapists, or osteopaths with a minimum of 3 years of work experience with SMT, who are member of their national association

*Exclusion criteria:* Not mastering the Dutch language

#### Data collection

With the exception of the e-mail and telephone contact, the participants and interviewer will not have had any previous contact to ensure that their relationship will not influence the interviews.

During the interview, questions will be asked to learn which factors influence treatment choice. Examples of questions that would be asked to patients during the interviews are: ‘How did the risk of relapse influence your choice of treatment modality?’; and ‘What are your expectations for the onset of the effect of the treatment?’. Questions that could be asked to health care providers are for example: ‘what factors do you think patients deem important when choosing SMT?’, or ‘How important are the costs of the treatment for the patient?’. Attributes identified from the literature review which are not mentioned by the interviewees, will be addressed directly in the interviews, as well as factors the project team deems important based on clinical expertise.

The interviews will either be held in person or online, in Dutch, voice recorded and transcribed verbatim. Participants will be recruited until data saturation will be reached.

#### Data management and analysis

A reflexive thematic analysis will be conducted to organize and interpret the procured data [31], using the six phases outlined by Braun & Clarke [31]. The first interviews will be coded by two interviewers independently of one another and later discussed until mutual understanding of the participants’ perspective is reached. An iterative process will be used in which the data collection and data-analysis will be alternated. After each interview the interviewer will revise the topic guide as new themes emerge and after the second interview the topic guide will be revised with other members of the project group. Subsequent interviews will only be coded by the interviewer. A summary of all transcripts will be written based on the first analysis and will be sent back to the participants to ensure their accuracy (i.e. member check) [29,32]. The interviews will be coded and analyzed using MaxQDA [33].

### Stage 3: the consensus group

#### Design

The purpose of the consensus group is to test and rank the attributes established in the first two stages with regard to their applicability for the DCE. The goal is to establish which attributes are the most important and will be incorporated in the DCE survey. However, we also aim to gain a better understanding of the attributes and preferences regarding the treatment of the low back using SMT.

#### Sampling

A purposive sampling strategy will primarily be used to ensure the three professional groups are represented evenly. Professionals and patients will be contacted through the network of the project team and/or the respective national associations (Nederlandse Chiropractie Associatie (NCA), MSG Science Network Physiotherapy and Nederlandse Vereniging voor Osteopathie (NVO)).

At least 2 consensus groups will be conducted, one with only practitioners and one with only patients, separated to create a safer environment, diminishing the chance of the feeling of social inequality between participants to reach a deeper level of understanding [29]. The size of the consensus groups is expected to be 6–8 subjects, based on literature and earlier experience [29].

Potential participants will be contacted by e-mail or telephone by the interviewer to ensure they fulfill the inclusion criteria. Information letters will be sent to the participant by e-mail, and written and verbal informed consent will be obtained prior to the conduct of the consensus groups. The participants will be given the opportunity to ask questions at the beginning and at the end of the consensus group, and will be explained that they can withdraw from participation at any time.

#### Inclusion- and exclusion criteria

##### Patients

*Inclusion criteria:* LBP patients that have started SMT treatment with a chiropractor, manual therapist, or osteopath during the last 3 months, over 18 years of age

*Exclusion criteria:* Not mastering the Dutch language

##### Health care providers

*Inclusion criteria:* chiropractors, manual therapists, and osteopaths with a minimum of 3 years of work experience with SMT, who are member of their national association.

*Exclusion criteria:* Not mastering the Dutch language

##### Data collection

The longlist of attributes emerging from stages 1 and 2 will be discussed amongst the project team members. The attributes not specific to SMT or applicable to SMT or the Dutch healthcare system will be excluded before commencing stage 3. This implies that the attributes that are associated with the characteristics of the therapist or the organization of the clinic will be excluded, such as proximity of clinic, cleanliness of clinic, friendliness of therapist or receiving a good explanation before onset of the therapy. These attributes are more generic and do not help to analyze the features specific to SMT. To narrow this list to the final list of attributes for the DCE, online consensus groups will be held using an interactive workshop design. Google Jamboard will be used to interactively communicate among each other. The attributes established in stage 1 and 2 will first be individually given a rating for importance, after which each attribute will be discussed among the participants of the consensus group. A two-step process comprising secondary ranking will be used where the participants will have the chance to alter their rating based on the discussion [34]. The consensus groups will be held online, in Dutch, voice recorded and transcribed verbatim and are expected to last 1,5 to 2 hours. A topic guide will be developed based upon the applicable attributes which emerged in the previous stages.

##### Data management and analysis

By calculating averages of the ratings, the participants assigned to the attributes, the ranking of the attributes can be established. As we are looking for the attributes influencing the care seeking behavior of patients, we will primarily examine the ratings of the consensus group held with patients. The project group will then discuss the reasoning behind the ratings and the grades of the focus group with health care providers. The 5–6 highest ranked attributes will then be incorporated into the choice sets of the DCE, if the project group concurs. The final selection of attributes and levels will be made following the qualitative research phase. Attributes that are expected to be incorporated into the choice sets of the DCE are 'effectiveness', 'costs', 'side effects', 'duration and frequency of treatment plan', and 'having to do home-exercises'. The levels of the attributes will represent realistic levels in daily practice, implying for instance for the costs, we use cost levels representing realistic out-of-pocket cost options. The levels will be based on literature and determined in consensus with the project group including health care providers active in this field.

To gain a deeper understanding of the prioritized attributes, a reflexive thematic analysis will be used in order to organize and interpret the procured data [31]. Similar to stage 2, the consensus group will be analyzed using the six phases outlined by Braun &

Clarke [35]. Both the consensus groups will be independently coded by two members of the project group and later discussed among them until intercoder agreement is reached. The consensus groups will be coded and analyzed by the primary investigator using MaxQDA.

## Part 2 – discrete choice experiment

A discrete choice experiment (DCE) is a survey method designed to examine relative importance of specific attributes in the choice between different treatments, as well as to identify which trade-offs participants are willing to make between these treatment attributes [19,20,36].

### Participant recruitment

Potential participants will be recruited through the network of Survey Engine. This international company has a panel of a wide variety of people. They will invite Dutch residents who have experienced a minimum of 6 weeks of LBP over the last 12 months to complete the survey.

Most published DCE's in healthcare have sample sizes between 100 and 300 respondents. An anticipated sample size of 300 respondents for our study will allow us to estimate main effects (with a minimum of 55 respondents needed according to the rule of thumb of Johnson and Orme ([37,38]), but also more elaborate analyses accounting for all two-way interactions. The rule of thumb for calculating the sample size for DCEs is:

$$N \geq 500 \frac{c}{t \times a}$$

here 'c' is equal to the largest number of levels of any attribute. 't' is the number of choice tasks and 'a' is the number of alternatives [39].

This, according to de Bekker-Grob [39], would necessitate about 222 respondents (with 18 choice tasks) to 267 respondents (with 15 choice tasks). Final estimates of the sample size will be made once the final choice about the number of attributes and levels is made.

### Inclusion- and exclusion criteria

- Inclusion criteria: Dutch residents over the age of 18 with self-diagnosed or diagnosed acute, sub-acute or chronic LBP. Having experienced at least 6 weeks of LBP in the last 12 months.
- Exclusion criteria: insufficient understanding of the Dutch language and participants who are currently being treated or have been treated with SMT for LBP in the past 2 years.

### Survey development

Before filling out the survey, informed consent will be obtained. The survey can be divided into two sections: 1) questions for eligibility, sociodemographic and clinical characteristics and comprehension questions, and 2) the actual DCE.

Section 1: This part of the survey will determine whether the participant is eligible. Questions will be asked whether the participant has experienced back pain in the last year and whether the patient has been treated with SMT during the last two years. If the participant is eligible to participate, questions will be asked to determine sociodemographic characteristics and the severity of the LBP (i.e. 'which therapist has treated you for your low back pain in the past year?', and the Quebec Back Pain Disability Scale). This will allow us to explore heterogeneity of responses among participants with different sociodemographic and clinical characteristics (e.g. severity and duration of the complaint, prior therapy, living area and level of insurance). Two sets of comprehension questions will be included: 1) an exercise to be completed before the actual DCE is administered, to teach the participants how to interpret the questions and to assess whether the participant has enough understanding of what is being asked; and 2) after completing the DCE, comprehension questions will be asked to assess the ease of understanding and answering the questions. The latter is done to test the validity of answers. Moreover, to test for uncertainty bias, it will be asked after each choice set how likely it is that the person would make this decision in real life circumstances. A five-point Likert scale (very unlikely – very likely) will be used for this task.

Section 2: this part of the survey is the actual DCE. Before commencing the DCE, there will be an explanation on SMT, the attributes and the levels, to ensure a common understanding by all participants. Quantitative information, such as probabilities and percentages, will be visualized using icon arrays. In the DCE, participants will be given a hypothetical scenario: the participant is asked to imagine he/she has a new episode of low back pain, which is very limiting. They have trouble putting on their socks and cannot stand or sit/stand/walk for too long periods of time and no treatment for this episode has been received so far. They will be presented with a series of choice tasks, each consisting of two different treatment choices and an opt-out (no treatment). A maximum of 15 choice tasks will be presented to participants. The treatment choices will be described by the attributes and levels established in part 1, these are the attributes and their corresponding options (e.g. attribute: Duration of treatment plan, levels: 1 month, 2 months, 3 months). An example of such a choice set can be found in Fig. 2. The choices will be unlabeled, which will emphasize the trade-offs that participants make in comparison to labeled alternatives [40].

To design the DCE, a Bayesian-d-efficient design will be created in specialized DCE software package NGene. The choice sets will be constructed with a d-efficient experimental design, following standard practices for discrete choice experiments in healthcare [41].

	Option 1	Option 2	Opt-out
<b>Duration and frequency of treatment plan</b>	4 treatments in 12 weeks	8 treatments in 4 weeks	N/A
<b>effectiveness</b>	25%	50%	20%
<b>Side effects</b>	0% kans	50% kans	N/A
<b>Costs</b>	15 euro per treatment	45 euro per treatment	N/A
<b>Having to do home-exercises</b>	Yes	No	N/A
	○	○	○

Fig. 2. Example of a choice set.  
Abbreviations: N/A: not applicable.

In a d-efficient design, the attribute levels of each choice situation are chosen such that the variance of the estimates of a choice model is minimized. d-efficient designs aim to maximize the statistical efficiency (precision) of estimated choice-model parameters, with a given number of choice questions. d-efficient designs enable to gather as much information as possible while not overburdening participants with a larger than strictly necessary number of choice tasks.

The survey will be pre-tested during 4 ‘think-aloud’ interviews, where the participants will be asked to complete the draft survey and state aloud their thought process to the investigator while doing so. The survey will also be tested by fellow researchers. The survey will be amended according to the responses of the participants, to ensure comprehensibility of the survey.

After 50 participants have returned the survey, it will be determined whether the response is as expected (i.e. confirming prior expectations about the preferences of participants). It will be evaluated whether adjustments need to be made to the experimental design, and whether the target patient numbers are sufficient.

#### Survey dissemination

All surveys will be administered online through Survey Engine, and will be preceded by an informed consent procedure.

#### Statistical analysis

Specialized software (NLogit) will be used to conduct the analyses of the DCE according to expert manuals [41]. Since each participant will complete several choice tasks, a panel model accounting for the panel nature of the data will be used. Internal validity will be tested by controlling for left/right-bias and monotonicity to ensure the participants read and answered the question regardfully. Also, logdata on the time to complete the whole survey and the DCE part of the survey are used to check the validity of the responses.

Based on the final choice of attributes and levels, the utility model will be specified. A multinomial logit model (MNL) will be estimated to establish the preferences of the overall patient population. To compare the goodness of fit of model specifications, we will use the AIC (Akaike information criterion), BIC (Bayesian information criterion) and log likelihood tests. Heterogeneity will be tested with a latent class model, which will determine the existence and the number of classes in the population (i.e. identifying different preferences across unobserved subgroups). This model is flexible in that the probability that sampled participants belong to a particular class (e.g. those who have a preference for quicker efficacy or those who prefer therapy only when there is no out-of-pocket payment) can be linked to covariates (e.g. age, sex) or clinical characteristics. A number of different specifications for the utility function will be used to select the most optimal function (e.g. categorical or numerical attribute levels, two-way interactions between characteristics). Based on the model’s coefficients, the SWEs will be estimated as a marginal rate of substitutions (e.g. the ratio of the mean coefficient ‘harms’ and mean coefficient for ‘expected outcome’) to examine the impact of SMT in comparison to the control group (between-group difference). Relative importance scores will be calculated based on the coefficients from the models, and sensitivity analyses will be run in order to evaluate their robustness.

#### Protocol validation

In part 1, the attributes influencing the care-seeking behavior of LBP patients who chose for SMT will be examined using qualitative methods. In part 2 (the DCE), these attributes will be used to establish the SWE for SMT treatment of LBP. With the SWE, the interpretation of randomized controlled trials can be enhanced by incorporating the patient’s perspective. This closes the research gap, as the SWE for non-surgical treatment of LBP has never before been identified using such a sophisticated method as a DCE. Identifying the risks, costs and inconveniences associated with SMT that patients are willing to accept in exchange for a specific level of effectiveness, will enable healthcare providers (HCPs) to deliver more patient-centered care.

## Limitations

A strength of our qualitative study is its triangulation: we will interview both patients and HCPs, and also send out member checks to increase the validity.

One strength of DCEs is that real-life scenarios are presented, and thereby, an attempt to close the gap between stated and revealed preferences. However, this remains an important issue that is difficult to resolve with the use of DCEs. By asking the participants how likely it would be that they would actually undergo this chosen treatment, an attempt is made to close this gap.

Another strength of the DCE study is the inclusion of comprehension questions to validate participants' understanding of the questions. Nevertheless, participants may interpret explanations of SMT, the attributes, and the levels differently than intended. To address this, we will attempt to enhance clarity through visual aids, such as images and videos. Additionally, the questionnaire will undergo pre-testing, using 'think-aloud' interviews to assess the clarity and understandability of the questions.

Finally, another strength of this study is the anticipated large sample size, allowing us to conduct robust analyses.

Beside strengths, there are also limitations. A known limitation of DCEs is that participants sometimes focus on only a subset of attributes when making choices leading to non-compensatory decision-making [38], meaning participants simplify the decision-making process by dismissing options where an attribute fails to meet a certain criterium and do not actively consider trade-offs. This selective attention could possibly impact the validity of the results. To evaluate this, questions will be asked which attributes influenced the answers given most.

Furthermore, participants will be excluded who have undergone SMT in the previous two years, to gain insight into the decision-making process of the population group potentially seeking a treatment for their LBP. However, participants with prior experience with SMT may respond differently than those who have never been exposed to SMT. In order to examine this, we will conduct a latent class analysis.

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## Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Three authors (LDLR, ADZ and SMR) are chiropractors who work in clinical practice, but have no direct financial interests linked with this survey.

## CRediT authorship contribution statement

**Lobke P. De la Ruelle:** Conceptualization, Writing – original draft, Writing – review & editing. **Annemarie de Zoete:** Conceptualization, Supervision, Funding acquisition. **Raymond Ostelo:** Conceptualization, Supervision, Funding acquisition. **G. Ardine de Wit:** Conceptualization, Supervision, Funding acquisition. **Marianne H. Donker:** Conceptualization, Supervision. **Sidney M. Rubinstein:** Conceptualization, Supervision, Funding acquisition.

## Data availability

No data was used for the research described in the article.

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## References

- [1] G. Olafsson, E. Jonsson, P. Fritzell, O. Hägg, F. Borgström, Cost of low back pain: results from a national register study in Sweden, *Eur. Spine J.* 27 (11) (2018) 2875–2881.
- [2] A. Wu, L. March, X. Zheng, J. Huang, X. Wang, J. Zhao, et al., Global low back pain prevalence and years lived with disability from 1990 to 2017: estimates from the Global Burden of Disease Study 2017, *Ann. Transl. Med.* 8 (6) (2020) 299.
- [3] Global, regional, and national burden of low back pain, 1990–2020, its attributable risk factors, and projections to 2050: a systematic analysis of the Global Burden of Disease Study 2021, *Lancet Rheumatol.* 5 (6) (2023) e316–ee29.
- [4] N.E. Foster, J.R. Anema, D. Cherkin, R. Chou, S.P. Cohen, D.P. Gross, et al., Prevention and treatment of low back pain: evidence, challenges, and promising directions, *Lancet* 391 (10137) (2018) 2368–2383.
- [5] Noninvasive treatments for acute, subacute, and chronic low back pain: a clinical practice guideline from the american college of physicians, *Ann. Intern. Med.* 166 (7) (2017) 514–530.
- [6] Anonymous Low Back Pain and Sciatica in Over 16s: Assessment and Management, 2020.
- [7] WHO Guideline For Non-Surgical Management of Chronic Primary Low Back Pain in Adults in Primary and Community Care Settings, WHO Guidelines Approved by the Guidelines Review Committee, Geneva, 2023.
- [8] S.M. Rubinstein, C.B. Terwee, W.J. Assendelft, M.R. de Boer, M.W. van Tulder, Spinal manipulative therapy for acute low-back pain, *Cochrane Database Syst. Rev.* 2012 (9) (2012) Cd008880.
- [9] S.M. Rubinstein, Ad Zoete, Mv Middelkoop, W.J.J. Assendelft, MRd Boer, MWv Tulder, Benefits and harms of spinal manipulative therapy for the treatment of chronic low back pain: systematic review and meta-analysis of randomised controlled trials, *BMJ* 364 (2019) 1689.
- [10] Koophandel Kv. Enorme Beweging in het Aantal Chiropractoren [Available from: <https://www.kvk.nl/pers/enorme-beweging-in-het-aantal-chiropractoren/>.
- [11] *Therapie NvM/Jaarbeeld 2022, 2023.*



- [12] Osteopathie NrvJaarverslag 2023, 2024.
- [13] R. Nuzzo, Scientific method: statistical errors, *Nature* 506 (7487) (2014) 150–152.
- [14] R.L. Wasserstein, N.A. Lazar, The ASA statement on p-values: context, process, and purpose, *Am Stat* 70 (2) (2016) 129–133.
- [15] S. Armijo-Olivo, The importance of determining the clinical significance of research results in physical therapy clinical research, *Braz. J. Phys. Ther.* 22 (3) (2018) 175–176.
- [16] C. Abdel Shaheed, S. Mathieson, R. Wilson, A.-M. Furrage, C.G. Maher, Who should judge treatment effects as unimportant? *J. Physiother.* 69 (3) (2023) 133–135.
- [17] M.L. Ferreira, R.D. Herbert, P.H. Ferreira, J. Latimer, R.W. Ostelo, D.P. Nascimento, et al., A critical review of methods used to determine the smallest worthwhile effect of interventions for low back pain, *J. Clin. Epidemiol.* 65 (3) (2012) 253–261.
- [18] V. Soekhai, C. Whichello, B. Levitan, J. Veldwijk, C.A. Pinto, B. Donkers, et al., Methods for exploring and eliciting patient preferences in the medical product lifecycle: a literature review, *Drug Discov. Today* 24 (7) (2019) 1324–1331.
- [19] E.W. de Bekker-Grob, M. Ryan, K. Fau - Gerard, K. Gerard, Discrete choice experiments in health economics: a review of the literature. (1099-1050 (Electronic)).
- [20] M.D. Clark, D. Determann, S. Petrou, D. Moro, E.W. de Bekker-Grob, Discrete choice experiments in health economics: a review of the literature, *Pharmacoeconomics* 32 (9) (2014) 883–902.
- [21] M. Ferreira, Research Note: the smallest worthwhile effect of a health intervention, *J. Physiother.* 64 (4) (2018) 272–274.
- [22] H.J. Hansford, M.D. Jones, A.G. Cashin, R.W.J.G. Ostelo, A. Chiarotto, S.A. Williams, et al., The smallest worthwhile effect on pain intensity of nonsteroidal anti-inflammatory drugs and exercise therapy for acute and chronic low back pain: a benefit-harm trade-off study, *J. Physiother.* 69 (4) (2023) 240–248.
- [23] M.L. Ferreira, R.D. Herbert, P.H. Ferreira, J. Latimer, R.W. Ostelo, M. Grotle, et al., The smallest worthwhile effect of nonsteroidal anti-inflammatory drugs and physiotherapy for chronic low back pain: a benefit-harm trade-off study, *J. Clin. Epidemiol.* 66 (12) (2013) 1397–1404.
- [24] D.H. Christiansen, N.B. de Vos Andersen, P.H. Poulsen, R.W. Ostelo, The smallest worthwhile effect of primary care physiotherapy did not differ across musculoskeletal pain sites, *J. Clin. Epidemiol.* 101 (2018) 44–52.
- [25] G.E. Ferreira, K. Howard, J.R. Zadro, M. O’Keeffe, C.C. Lin, C.G. Maher, People considering exercise to prevent low back pain recurrence prefer exercise programs that differ from programs known to be effective: a discrete choice experiment, *J. Physiother.* 66 (4) (2020) 249–255.
- [26] M.E. Klojgaard, C. Manniche, L.B. Pedersen, M. Bech, R. Sogaard, Patient preferences for treatment of low back pain—a discrete choice experiment, *Value Health* 17 (4) (2014) 390–396.
- [27] T.G. Poder, M. Beffarat, Attributes underlying non-surgical treatment choice for people with low back pain: a systematic mixed studies review, *Int. J. Health Policy Manag.* 10 (4) (2021) 201–210.
- [28] A.-B. Zakrisson, K. Theander, A. Anderzén-Carlsson, The experience of a multidisciplinary programme of pulmonary rehabilitation in primary health care from the next of kin’s perspective: a qualitative study, *Primary Care Respirat. J.* 22 (4) (2013) 459.
- [29] J. Green, N. Thorogood, *Qualitative Methods for Health Research*, SAGE Publications, 2013.
- [30] K.M. Hjellev, O. Skutle, O. Førland, H. Alvsvåg, The reablement team’s voice: a qualitative study of how an integrated multidisciplinary team experiences participation in reablement, *J. Multidiscip. Healthc.* 9 (2016) 575.
- [31] V. Braun, V. Clarke, Reflecting on reflexive thematic analysis, *Qual. Res. Sport Exer. Health* 11 (4) (2019) 589–597.
- [32] J. Mouton, in: *Understanding Social Research*: JL, van Schaik, 1998, p. 272.
- [33] VERBI SoftwareMAXQDA 2022, VERBI Software, Berlin, Germany, 2021.
- [34] S.S. McMillan, F. Kelly, A. Sav, E. Kendall, M.A. King, J.A. Whitty, et al., Using the Nominal Group Technique: how to analyse across multiple groups, *Health Serv. Outc. Res. Methodol.* 14 (3) (2014) 92–108.
- [35] V. Braun, V. Clarke, One size fits all? What counts as quality practice in (reflexive) thematic analysis? *Qual. Res. Psychol.* 18 (3) (2021) 328–352.
- [36] V. Soekhai, E.W. de Bekker-Grob, A.R. Ellis, C.M. Vass, Discrete choice experiments in health economics: past, present and future, *Pharmacoeconomics* 37 (2) (2019) 201–226.
- [37] B. Orme, *Sample Size Issues For Conjoint Analysis Studies*, Sawtooth Software, Sequim, 1998 Sawtooth Software Technical Paper.
- [38] R. Johnson, B. Orme, *Getting the Most from CBC*, Sawtooth Software, Sequim, 2003 Sawtooth Software Research Paper Series.
- [39] E.W. de Bekker-Grob, B. Donkers, M.F. Jonker, E.A. Stolk, Sample size requirements for discrete-choice experiments in healthcare: a practical guide, *Patient* 8 (5) (2015) 373–384.
- [40] E.W. de Bekker-Grob, L. Hol, B. Donkers, L. van Dam, J.D.F. Habbema, M.E. van Leerdam, et al., Labeled versus unlabeled discrete choice experiments in health economics: an application to colorectal cancer screening, *Value Health* 13 (2) (2010) 315–323.
- [41] F. Reed Johnson, E. Lancsar, D. Marshall, V. Kilambi, A. Mühlbacher, D.A. Regier, et al., Constructing experimental designs for discrete-choice experiments: report of the ISPOR conjoint analysis experimental design good research practices task force, *Value Health* 16 (1) (2013) 3–13.