



BMJ Open Healthcare professionals' knowledge, attitudes and practices toward deprescribing: a protocol of cross-sectional study (Desmedica Study—Brazil)

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ABSTRACT

Background Deprescribing is the planned and supervised process of dose reduction or stopping of medication that might be causing harm, or no longer be of benefit. It is an activity that should be a normal part of care/the prescribing cycle. Although now broadly recognised, there are still challenges in its effective implementation.

Objectives To develop and validate an instrument to measure Brazilian healthcare professionals' knowledge, attitudes and practices towards deprescribing.

Methods This study will include the following steps: (1) development of the preliminary instrument; (2) content validation; (3) pilot study; (4) evaluation of psychometric characteristics. After the elaboration of items of the instrument through the literature review, we will use a hybrid Delphi method to develop and establish the content validity of the instrument. Further, a pilot survey will be performed with 30 healthcare professionals. Finally, for the evaluation of psychometric characteristics, a cross-sectional study will be accomplished with a representative sample of different healthcare professionals from different Brazilian states using respondent-driven sampling. Exploratory factor analysis and confirmatory factor analysis will be performed. For assessing the model fit, we will use the ratio of χ^2 and df (χ^2/df), comparative fit index, the goodness of fit index and root mean square error of approximation. In addition, the reliability of the instrument will be estimated by test–retest reproducibility and Cronbach's alpha coefficient (α).

Ethics and dissemination The Ethics Committee for Research at the University of Sorocaba (ethics approval number: 3.848.916) approved the study. Study findings will be circulated to healthcare professionals and scientists in the field through publication in peer-reviewed journals and conference presentations.

INTRODUCTION

Polypharmacy is commonly defined as the concomitant use of five or more drugs at the same time.¹ Although in many instances the use of multiple medicines may be clinically appropriate, when inadequate, it increases

Strengths and limitations of this study

- Understanding how deprescribing is perceived and implemented across healthcare professionals and practice settings in order to identify gaps, barriers and enablers, helping the development and implementation of interventions to improve the appropriate discontinuation of medications.
- This is the first study in Brazil to attempt to develop a validated instrument able to assess healthcare professionals' knowledge, attitudes and practices toward deprescribing.
- Although this study will propose a validated instrument applicable to Brazilian healthcare professionals, it might overlook some contextual factors that might affect the deprescribing process across different settings.
- The heavy workload of healthcare professionals and the number of items in the instrument may compromise participants' compliance in this study.

the risks of adverse events and it is associated with poor health outcomes, including medication non-adherence, cognitive impairment, fragility, falls and functional disability.²

Deprescribing has been proposed as an activity that should be a part of care and the prescribing cycle. It is defined as 'the process of withdrawal of an inappropriate medication, supervised by a healthcare professional with the goal of managing polypharmacy and improving outcomes'.³ Systematic reviews have shown that deprescribing is safe and can be achieved successfully, especially in older adults with multimorbidity.^{4 5} Data suggest that it is associated with numerous health benefits including improvement in cognition, a reduction in falls, a decrease in fractures, better medication adherence and improvement in the quality of life.^{4 5}

Currently, there is increasing recognition of the need for implementation of deprescribing in clinical practice.⁶ However, the evidence on the effectiveness of deprescribing interventions is limited across settings. Further studies are needed in order to develop more effective strategies for this process, as well as to overcome barriers related to healthcare professionals and patients.⁷⁻⁹

Stopping or reducing the dose of medications in clinical practice is a challenge for healthcare professionals.¹⁰ This may, in part, be due to limited evidence^{11 12} on deprescribing, time and workflow constraints, and perceived self-efficacy. In addition, they often have to balance a multitude of factors including the disease(s) the patient may have, the benefit–risk profile of medicines prescribed, the patients' personal views and the opinions of other prescribers. Thus, an understanding of the enablers and barriers to deprescribing among healthcare professionals is the first step for planning and evaluating future interventions that enable the implementation of this practice in patient care.¹³

Although many studies have explored the perceptions, knowledge, attitudes and practices toward deprescribing in order to identify the barriers and enablers to implementation of this process into clinical practice from general practitioners and physicians,¹⁴⁻²⁷ only one study validated a survey instrument to measure these outcomes.²⁸ This instrument was limited to primary care providers.

A qualitative systematic review which included 21 studies indicated that barriers to deprescribing included existing organisation systems and policies, self-perceived

restriction in the ability to be involved in medication-related issues, and lack of knowledgeable and skilled personnel.¹³

In Brazil, deprescribing is still a topic little discussed among healthcare professionals. Recently, some efforts to develop and adapt tools for the Brazilian context have been observed.²⁹⁻³¹ However, to date, there are no published studies exploring the knowledge, attitudes and practices of healthcare professionals toward deprescribing in Brazil.

Studies proposing to understand and conceptualise prescribers' barriers and enablers are required to inform the development of a deprescribing intervention best suited for the needs of the Brazilian context. For this reason, this study aims to develop and validate an instrument within the Brazilian context, which is able to assess the knowledge, attitudes and practices of healthcare professionals related to deprescribing.

METHODS

This is a protocol of a cross-sectional study aiming to develop and validate an instrument to measure Brazilian healthcare professionals' knowledge, attitudes and practices toward deprescribing.

This study protocol has been approved by the Ethics Committee for Research at the University of Sorocaba (number: 3.848.916) and will be carried out from November 2020 to January 2021.

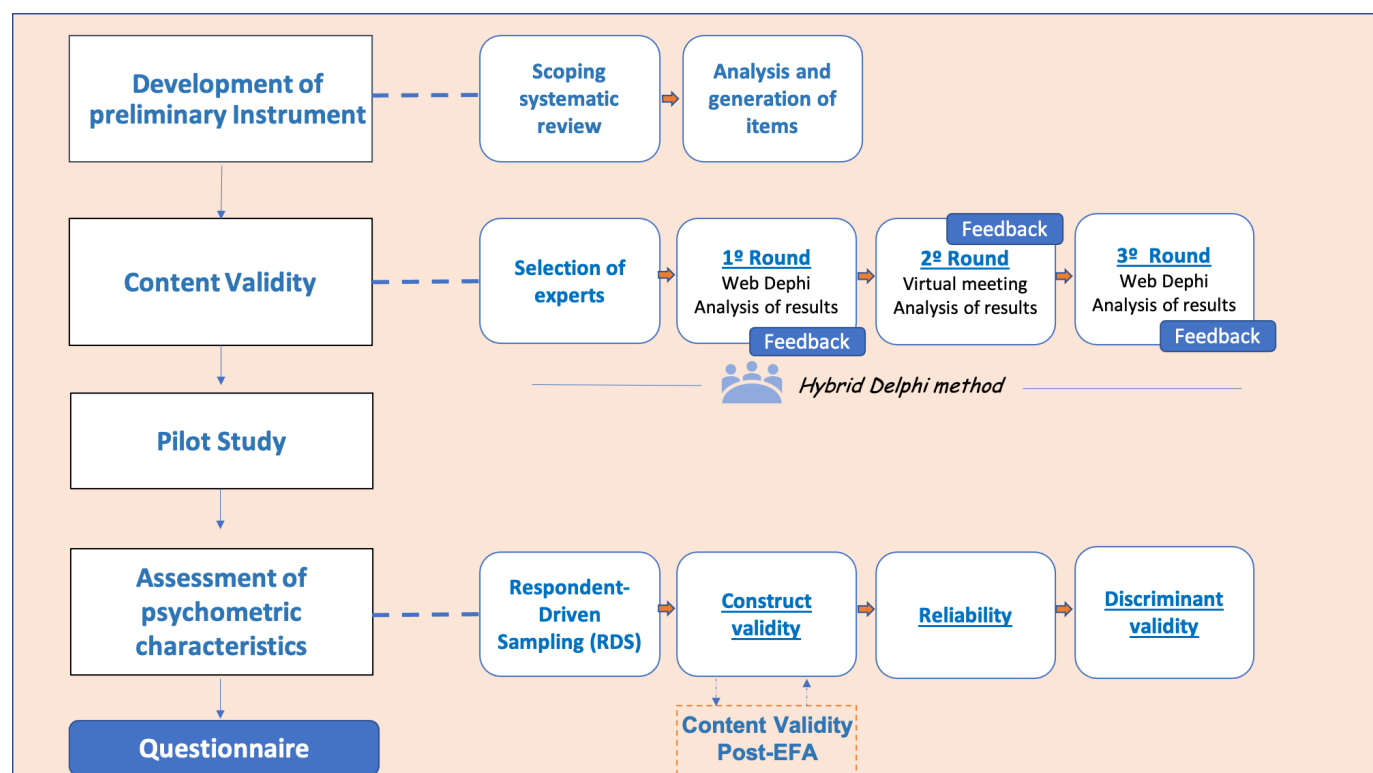


Figure 1 Study steps.

Development and validation of the instrument

In this study, the development and validation of the instrument will include the following steps (figure 1): (1) development of preliminary instrument; (2) content validation; (3) pilot study; (4) assessment of psychometric characteristics.

Development of preliminary instrument

Search strategy to support the theoretical framework

In order to establish a theoretical framework on the evaluated dimensions of barriers and enablers of deprescribing, we will conduct a scoping systematic review to examine factors that affect deprescribing implementation and to obtain sources of possible instruments already used in other countries to address the study's aim. Searching will be conducted in PubMed, CINAHL and LILACS using the following keywords combined by Boolean operators: “deprescription(s)”, “deprescribing”, “cessation”, “withdrawal”, “polypharmacy”, “knowledge”, “attitudes” and “practice”.

After retrieving studies, we will be checking the following aspects:

- ▶ Knowledge, attitudes, practices toward deprescribing.
- ▶ Barriers, equity and enablers to implementation of deprescribing across healthcare settings.
- ▶ Components of the conceptual framework which are the most important for establishing the instrument's dimensions.
- ▶ The most important items for representing/assessing the instrument's dimensions.
- ▶ Additional dimensions or items needed when considering a specific challenging behaviour.

Analysis and generation of items

For analysis and generation of items, a conceptual framework will be proposed by the research team based on two previous conceptual frameworks.^{32 33} This framework will be used to critically evaluate findings from studies selected and is composed of three major domains: Knowledge, Attitude and Practice. Each of these major domains is further divided into subcategories or constructs (see figure 2).

Content validity

Content validity is defined as the degree to which elements of an instrument are relevant to and representative of the construct to be measured.^{34 35} All elements of the instrument (eg, items, instructions, response formats, scoring) that can potentially impact the scores obtained and the interpretations made should be subjected to content validation.

In this study, we will use a hybrid Delphi method to develop and establish the content validity of the preliminary instrument, adopting the RAND approach.³⁶ This consensus method is composed of a round of the online instrument (e-Delphi), and subsequently, a second round which involves a virtual meeting to facilitate debate and resolve disagreements.³⁷ This hybrid Delphi process has the advantage of both methods of information transfer: anonymous research with a group of geographically dispersed specialists and a face-to-face discussion, with the opportunity for clarifications, in real time, to exchange points of view and resolve uncertainties.³⁸ However, the virtual meeting must be well structured and must be held under favourable conditions (good atmosphere and general environment) with a moderator to contain the influence of dominant personalities.³⁹ Differently

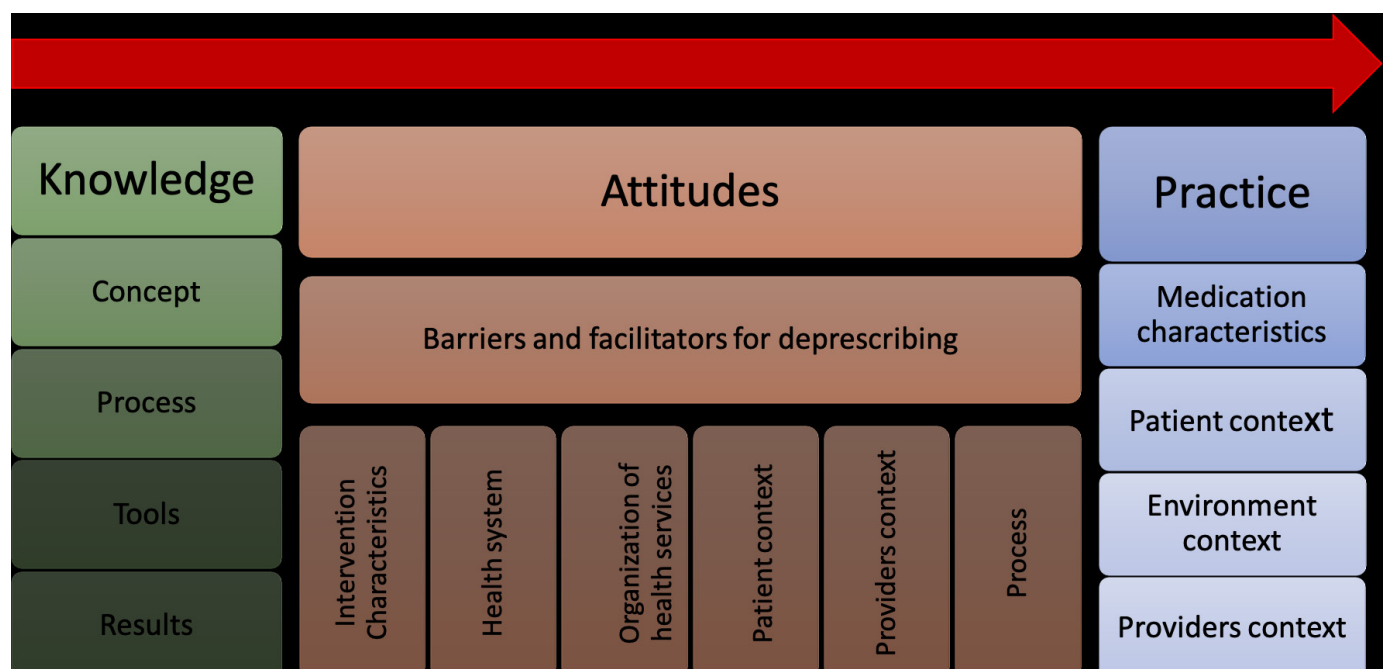


Figure 2 Conceptual framework.

from the Delphi hybrid reported by other authors,³⁵ we use the Delphi to prioritise the questions drawn from the literature reviewed or deduced from the theoretical approach employed in the first round, and then employ the nominal group technique to refine the questionnaire. Finally, in the third round, we will use Delphi method to establish the content validity.

After the factorial validity, we will conduct the content validity of the post-factorial analysis questionnaire using Delphi method in order to verify that no relevant item was removed due to factor analysis. All specialists who participated in the first part of the content validation will be invited to participate in this stage.

Selection of experts

Brazilian experts in medicine, pharmacy, and nursing with academic and/or clinical backgrounds will be selected primarily based on their experience in the field of deprescription and their experience in caring for people with multimorbidity and polypharmacy. The criteria for selecting experts in addition to the experience in the themes reported above will consider the scientific production of the last 2 years in the core journal. Those who have experience and greater production in impact core journal will be selected.

They will be identified through the following ways: directly through researchers' contacts and networks, via a review of literature or via the Lattes platform of the National Council of Technological and Scientific Development. This platform is an information system about scientific production, technology, and innovation related to individual researchers and institutions working in Brazil. This database is publicly available (<http://lattes.cnpq.br/>) and maintained by the Brazilian federal government. The experts selected will be contacted individually by the researcher via email and/or phone. In addition, we will use snowball sampling by asking selected experts to suggest individuals nationwide with recognised experience in the field. Since the new indication is from experts previously selected, we will contact them individually by email and/or phone and check if they address the inclusion criteria about experience in both fields.

The initial document sent to the experts will contain an introductory text about the objectives of the study and the process of consensus. After acceptance and signature of the informed consent form, a cover letter and a link that will give access to the electronic form will be sent.

According to Cosmin methodology for evaluating the content validity,⁴⁰ an adequate number of panel members should have at least 20 experts. Considering that 35% of the invited experts and their indications will probably not accept the invitation, or will give up during the consensus process, we will invite at least 30 experts to participate in this study.^{40 41}

Rounds

The Delphi process will involve three rounds. These will include iterative multistage processes designed to

combine opinion into group consensus. After each round, we will send the summarised information and feedback in order to allow the opportunity for experts to reconsider their original responses and perhaps change their opinion.

First round

The experts will be asked to rate each item based on theoretical dimension, relevance, clarity, simplicity and ambiguity using the 4-point Likert scale.^{42 43} In addition, the experts will be invited to suggest new items/modifications. For each item, a space for comments will be provided.

Second round

Experts will be invited to participate in a virtual meeting, offering each expert the opportunity to discuss ideas, their own experiences and the available evidence. This is an important part of the RAND method and it is the role of the facilitator to ensure that all problems and views are equally discussed.³⁶ The format of the consensus meeting will comprise a short study overview, a presentation containing a summary of the results and the number of items that achieved consensus. Discussion of each item will then be followed by an anonymous scoring method by those at the virtual meeting; therefore, the assessments of panel participants who choose not to contribute to the discussion are the same as those who can dominate the procedures.

Third round

The experts will review the items in which there were doubts during the virtual meeting. In addition, we will provide feedback from the previous round. At the end of the instrument, they also will be requested to assess the instrument according to whether all the items refer to relevant aspects of the construct to be measured and whether all the items together comprehensively reflect the construct.⁴⁴

Each round will be conducted over a period of 30 days. After receiving responses from experts, comments/suggestions from the expert panel on each item and on the instrument will be summarised to guide the instrument revision. All proposed modifications will be discussed by the research team.

The complete process of construction of the instrument items and their validation is summarised in [figure 1](#).

Definition consensus

Descriptive statistics like agreement proportions between the experts will be calculated for each item.

In the first round, we will use two agreement indices for establishing the content validation: item-content validity index (I-CVI) (the number of experts scoring 3 or 4, divided by the total number of experts) and the modified kappa (κ^*).⁴⁵ Items with an I-CVI-rated score of 0.78 or above and κ^* score greater or equal to 0.74 for all rated attributes will be considered validated.⁴⁵

In the second and third rounds, we will evaluate the proportional level of agreement about each item. We will use the traditional 9-point scale (1=extremely irrelevant to 9=extremely relevant). The participants' responses will be categorised as irrelevant (1–3), equivocal (4–6) and relevant (7–9). For each item, the consensus will be reached if at least 80% of the participants' votes belong to the same category (1–3, 4–6 or 7–9). Items that do not reach consensus will be reviewed and submitted for the next round. After the third round, items that do not reach consensus will be excluded.

Criteria for dropping items at each round

If 80% or more of the experts' votes belong to the irrelevant category (1–3), the item will be excluded from the instrument.

Pilot test

Before performing the psychometric analysis on the intended interviewees, it is advisable to test the instrument items in a small pilot sample (~30 participants). This pilot sample will be invited to give their opinion on the general instrument separately after completing the survey. This is an opportunity for the instrument developer to know if there is confusion about an item and if the participants have suggestions for possible improvements on the items. In addition, the researchers can test if the sampling and data collection is adequate for proposed objectives and methodology.

Assessment of psychometric characteristics

This step is a cross-sectional study, with a probabilistic sampling design.

Participants

The sample will be composed of physicians, nurses (registered nurses and clinical nurses) and pharmacists who are currently working in clinical practice. The estimated minimum sample size will be based on the requirement of 5–10 subjects per model parameter.⁴⁶ Given that the instrument's estimated number of parameters will be around 40 items, our final sample should have between 200 and 400 respondents.

Sampling and data collection

Respondent-driven sampling will be used to recruit the study participants.⁴⁷ This method combines elements of snowball sampling and network analysis to achieve high statistical validity in a sampling setting where the target population cannot be reached in a systematic manner.⁴⁸ The first step is the selection of the initial participants, which are called 'seeds'.⁴⁷ In this study, prior to recruitment, the research team will map potential seeds from healthcare professionals' databases (ie, database from the Brazilian Federal Council of Pharmacy, Brazilian Federal Council of Nursing and other societies of health professionals), according to demographical characteristics, geographical regions, expertise, and type of healthcare services in order to include a diverse and potentially more

representative sample.⁴⁸ The number and selection of seeds will be based on the diversity of the study population since we intend to apply the instrument in all regions of Brazil. We will invite 50–100 seeds that will receive an explanation of the study project and a link with direct access to the survey. The instrument will include the developed instrument, as well as items related to sociodemographic characteristics (gender, age and educational level), work years and type of healthcare service (hospitals, ambulatory, public, private). After completion of the instrument, each participant will be instructed to recruit others, with recruitment being restricted to a maximum of three recruits per person. At the end of the questionnaire, they will give information about other contacts such as email and phone numbers. Subsequently, recruited individuals will continue the process such that multiple waves of recruitment occur until the desired sample size is reached.

Inclusion criteria

Healthcare professionals who are currently working in clinical practice.

Exclusion criteria

Professionals on leave from work for limited or unlimited time during the period of application of the instrument, and professionals who are retired from clinical practice.

Psychometric sensitivity

Items' psychometric sensitivity is defined as the ability of an item to discriminate structurally different individuals. It will be assessed by comparison with the normal distribution by estimation of the skewness (sk) and kurtosis (ku) of each item's distribution. Skewness measures asymmetry, or the extent to which scores tend to fall at extreme ends of the range; while kurtosis measures 'peakedness,' or the extent to which scores cluster around the mean. Absolute values of sk and ku smaller than 3 and 7, respectively, will be considered indicative of psychometric sensitivity and/or not deviating enough from the normal distribution to recommend against further psychometric analysis.⁴⁹

Construct validity

Construct validity is defined as the extent in which a set of questionnaire items represents the construct intended to be measured.⁵⁰ In order to assess the construct validity of the instruments, we will apply the factorial validity.

Factorial validity

Factorial validity is related to the degree to which the scores of an instrument are an adequate reflection of the dimensionality of the construct to be measured.⁵¹ It will be examined by exploratory factor analysis (EFA) and confirmatory factor analysis (CFA). The sample adequacy for conducting factor analysis will be evaluated by two different tests: the Kaiser-Meyer-Olkin test and Bartlett's sphericity test. Values greater than 0.5 and $p < 0.05$ will be acceptable, indicating that the correlation matrix is factorable.⁴⁶

After confirming that the correlation matrix will be factorable, EFA will be performed to identify the underlying relationships between the measured items and to reduce the number of questionnaire items.⁴⁶ When conducting an EFA, a researcher has to make decisions regarding the extraction method, the number of factors to retain, the rotation method and the method for calculating scores. In order to select the most appropriate method for extraction, we will evaluate whether the data are normally distributed or significantly non-normally distributed through the Kolmogorov-Smirnov test.⁵² If data are relatively normally distributed, the maximum likelihood is the best choice. On the other hand, if the assumption of multivariate normality is violated, it is recommended the use of the principal factor methods such as principal axis factors (PAFs). PAF is the most robust method, it can be used when normality is violated and demonstrated the ability to recover weak factors. In addition, the results from this last method are more generalisable when submitting hypothesised models to a CFA.⁵³

Regarding the rotation method, initially, we will apply an oblique rotation in order to examine the factor pattern matrix and factor correlation matrix.⁵⁴ If factors are not correlated, we will use the orthogonal rotation method. Finally, for determining the number of factors to retain, we will use a combination of the following methods: eigenvalue of 1 or greater, scree plot and parallel analysis minimum average. The items with factorial loads greater than 0.5 will be extracted as they are of great practical relevance and they adequately define the factors.^{55 56}

Subsequently, CFA will be conducted to establish the most appropriate factor structure of the instrument. Thus, after one model is created, the researchers will test how well the model fits the data. It will be considered acceptable if $\chi^2/df < 2$, comparative fit index < 0.95 , root mean square error of approximation < 0.06 and Tucker-Lewis Index < 0.95 .⁵⁵

Reliability

The term reliability refers to the ability to reproduce a consistent result in time and space, or from different observers, presenting aspects on coherence, stability, equivalence and homogeneity.⁵⁷ To estimate the reliability, both the internal consistency and stability will be evaluated.

Internal consistency

The internal consistency aims to evaluate if the domains of an instrument measure the same characteristic, that is, the average correlation between all the construct items. In this study, we will use a standardised Cronbach's alpha coefficient (α) to establish the internal consistency where Cronbach's α of 0.7–0.8 will be considered satisfactory, 0.8–0.9 will be good and 0.9 will be excellent.^{58 59}

Stability

The stability evaluates the consistency of repeated measurements. It will be performed using test–retest method by verifying the intraclass correlation coefficient. This procedure measures the stability of the scores of a stable construct obtained from the same person at two different times. Values above 0.70 will be considered satisfactory, which suggests that the items measure the same way as the constructs, and are therefore appropriate.⁵⁰

A number of at least 50 subjects will answer the same instrument at two different moments with an average interval of 7 days, in order to verify the reproducibility of the instrument by test–retest.

Discriminant validity

Discriminant validity aims to identify differences between groups in which it is theoretically expected to find these differences. It allows evaluating whether the tested instrument discriminates the differences between different groups.⁵¹ In this study, discriminant validity will be evaluated by comparing results between participants grouped by characteristics (sex, age, types of professional, time since graduation, highest professional degree and setting of work) using Student's t-test or analysis of variance. Significantly, different results ($p < 0.05$) in the participants grouped by characteristics will indicate a good discriminating validity.⁵¹

Data analysis

Data analyses will be performed using SPSS (V.22.0) and Stata (V.16.0).

Patient and public involvement

Patient and public involvement was not sought at protocol formulation stage but will be so in the implementation stage and reported accordingly.

DISCUSSION

Although deprescribing has become an increasingly important topic of interest in recent years, little quantitative research among healthcare professionals has been done on barriers and enablers of deprescribing in clinical practice.^{8 23 28 60 61} For this practice to be fully implemented, it is essential to clarify possible barriers and enablers among healthcare professionals.

In Brazil, no studies were found that develop and adapt the instruments to evaluate the process of deprescribing, or that estimate the psychometric qualities of these instruments. Although psychometric studies involve complex and systematic procedures that require theoretical and methodological rigour, they increase the quality of the data to be collected, promoting a better understanding of a variety of behaviours from healthcare professionals. However, despite the relevance of these steps, they have not yet been widespread in all fields, especially in deprescribing. The development of a validated instrument will

allow identifying critical components of successful intervention for future applications in clinical practice.

After completing the necessary steps to make the instrument available to the Brazilian context, it is suggested that it may become a useful tool for identifying health-care professionals who are less prepared to implement deprescribing and may, therefore, allow the development of targeted education and/or support as well as future guidelines.

In addition, it may serve as a useful tool in research activities in order to explore barriers where deprescribing has not been successful, or where educational approaches are employed, or as a monitoring tool to assess the change of perceptions and attitudes.

Study limitations

Although we will combine a set of different methods which will help to provide a comprehensive range of factors that can influence the implementation of deprescribing in clinical practice, healthcare professionals' perceptions and attitudes toward deprescribing are complex and multifaceted, and therefore, the instrument may not capture all the nuances of perspectives on deprescribing.

In addition, several other types of validity will not be assessed in this study such as external/predictive validity and criterion validity. Future studies should perform these types of validation.

Finally, although we describe a robust method to develop and validate an instrument following the recommendations from different guidelines,^{36 38 40 41 52 56 62} the cross-sectional design can compromise the directionality of associations, thus, the results from this study will not elucidate the cause-effect relationship between the variables.

Ethics and dissemination

The Ethics Committee for Research at the University of Sorocaba approved the study protocol (ethics approval number: 3.848.916). During the three stages of the study, we will obtain informed consent from each participant prior to taking part in the study. The study results will produce at least two articles published in scientific journals. Additionally, brief reports of the findings will be disseminated to healthcare professionals at conferences and strategic meetings.

The study output will provide a psychometrically valid and reliable tool for evaluation. It is also hoped the instrument will be effective to assess key features of successful deprescribing and to identify areas for further development of this intervention to increase their effectiveness and impact. Future research will also be needed to assess the sensitivity of the instrument to measure changes after interventions in randomised controlled trials.

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Contributors All authors participated in the preparation of the manuscript and agreed to the submitted version of the paper. FRM and LCL had the original idea and they developed the study protocol. NMC, LCL and FRM drafted the manuscript.

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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.

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