"Please do take into account that this is a translation of the original French version validated in the Quality Management System (QMS) of Cliniques universitaires Saint-Luc through the SharePoint PaCo GED. Therefore in case of doubt, differences, inconsistency or discrepancy in this English version, the French version shall prevail"

1. TITLE PAGE

Development and validation of a health behaviour theory-based questionnaire to assess the willingness of older adults and informal caregivers to deprescribe (HBQtD)

Protocol identification: HBQ23

Sponsor: UCLouvain (ARC, Actions de Recherche Concertée)

Development and validation of a health behaviour theory-based questionnaire to explore the willingness of older adults and informal caregivers to deprescribe (HBQtD)

This study is an instrument development and validation project that will last about a year.

Sponsor: UCLouvain (ARC-Di-Prescribe), Place de l'Université 1, 1348 Louvain-la-Neuve

Sponsor representative: Professor Spinewine, LDRI Avenue Mounier 72/B1.72.02 1200 Woluwe-Saint-Lambert; phone number: +32 2 764 73 52

Principal investigator: Professor Van den Broucke, 10 Place Cardinal Mercier, Bureau D215 1348 Louvain-la-Neuve; phone number: +32 (0) 10 479046

Co-investigator : Alves Jorge, affiliation at IRSS, Clos Chapelle-aux-Champs, 30, Bte B1.30.15 1200 Bruxelles ; phone number : +32 (0)468367612

Professeur Spinewine is the coordinator of all Di-Prescribe project. PI – Professor Van den Broucke will conduct the study according to the GCP and applicable regulations. So, PI will supervise each stage of questionnaire validation process, and ensure that the protocol is respected. In addition, PI will provide safety updates and periodic progress reports, and he will notify the end of the study and the final study report. Under PI's supervision, the co-investigator will develop the different stages for validating the questionnaire. Professeur Spinewine and Professeur Van den Broucke will follow and provide feedback at each stage of the validation process. A meeting with the whole research team is scheduled every month to discuss progress, difficulties and results obtained at each stage of the questionnaire validation process.

Version History

Version	Approval Date		Changes
1		Original	
2	11/08/23	Amendment	Anonymity of healthcare professionals included in the study and their relationship with the sponsor; HLS19_Q12 and MHLCS questionnaire administration
3	25/09/23	Amendment	Modified Schedule of Activities
4		Amendment	

2. SIGNATURE PAGE

SPONSOR REPRESENTATIVE

INVESTIGATOR(S)

I agree to conduct this study in accordance with the design and specific provisions of this protocol and will only make changes in the protocol after notifying the sponsor.

I understand that I may terminate or suspend enrolment of the study at any time if it becomes necessary to protect the best interests of the study subjects.

I agree to personally conduct or supervise this study and to ensure that all associates, colleagues, and employees assisting in the conduct of this study are informed about their obligations in meeting these commitments.

I will conduct the study in accordance with the protocol, Good Clinical Practice, the Declaration of Helsinki, and the moral, ethical and scientific principles that justify medical research. The study will be conducted in accordance with all relevant laws and regulations relating to clinical experimentation and the protection of patients.

I will ensure that the requirements relating to Ethics Committee review and approval are met.

I agree to maintain adequate and accurate records and to make those records available for audit and inspection in accordance with relevant regulatory requirements including the provision of direct access to data and source documents.

I agree to promptly report to the Ethics Committee any changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without Ethics Committee approval, except where necessary to ensure the safety of study participants.

3. PROTOCOL SYNOPSIS

Name of Sponsor UCLouvain (ARC, Actions de Recherche Concertée – Di-Prescribe)
Title of Study **Development and validation of a health behavior theory-based questionnaire to examine the willingness of older adults and informal caregivers to deprescribe**
Service(s) in which the experimentation is taking place Primary care setting, nursing homes in Brussels and Wallonia
Publication (reference)
Studied period : September 2023 to october 2024
Objectives: - Primary: to develop and validate a health behavior theory-based questionnaire to examine the older adults' and informal caregivers' determinants of deprescribing behavior - Secondary: assess the psychometric properties of this new instrument
Hypotheses The use of health behavioral constructs in the development of an assessment tool will have greater predictive validity than that of existing tools
Study Design Questionnaire development and validation that involve an item development and validation stage
Number of planned patients: - 345 older adults; 345 informal caregivers
Main criteria for inclusion (inclusion/exclusion criteria) **Inclusion criteria:** Older adult population: • Age 60 years or older; • Taking at least 5 medications daily; • Having at least one chronic condition; Informal caregiver (such as spouse, family/ friend caregivers): • Self-identified as a caregiver of an older adult who has 60 years old or older, that are taking at least 5 medications daily and having one or more chronic condition; • The care recipient lived in the community or in a nursing home. **Exclusion criteria:** Older adult population: • Suffering from psychiatric trouble; • Past or present drug or alcohol dependency; • Having a terminal illness; • Inability to complete a written questionnaire in French due to a functional or cognitive impairment; • Inability to understand and express oneself in French.

Informal caregiver population: • Caregiver age under 18 years old; • Caregivers who are paid for the care they provide; • Caregiver inability to give consent and complete a written questionnaire in French; • Caregiver inability to understand and speak in French.
Procedures: Schedule of assessments – Study Flowchart
Statistical Considerations Methods that will be used to validate the questionnaire: face validity, content validity, construct validity, internal validity and test-retest reliability. To assess the psychometric properties of the questionnaire, an exploratory factor analysis (EFA) will be performed – construct validity. Face and content validity will be performed by qualitative methodology, and using the content validity ratio (CVR). Internal validity will be assessed using the Cronbach's alpha and omega coefficient, and test-retest reliability will be investigated using the Cohen's kappa and Interclass correlation coefficient (ICC). Logistic regression will be performed to investigate the association between the determinants and the intention, or deprescribing behavior.

4. SCHEDULE OF ACTIVITIES

Activities/ Months	2023												2024								
	06	07	08		09		10		11		12		01	02	03	04	05	06	07	08	09
			15d	15d	15d	15d	15d	15d	15d	15d											
Questionnaire development and protocol redaction																					
Ethics committee																					
Contact institutions and organizations for recruitment																					
Cognitive pre-test with OA and IC																					
Round with HCP																					
FG with HCP																					
Round with OA and IC																					
FG with OA and IC																					
Recruitment for questionnaire validation																					
Results analysis																					
Preparing publication																					

OA: older adults; IC: informal caregivers; HCP: healthcare professionals; FG: focus group

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5. LIST OF ABBREVIATIONS AND DEFINITIONS

BMQ	Beliefs about medicines
BZD	Benzodiazepines
CVR	Content validity ratio
EFA	Exploratory factor analysis
HCP	Healthcare professionals
HBM	Health Belief Model
HBT	Health Behavior Theory
FG	Focus group
HL	Health literacy
HCP	Healthcare professionals
IC	Informal caregivers
ICC	Interclass correlation coefficient
NH	Nursing home
OA	Older adults
PATD	Patient Attitudes Towards Deprescribing
rPATD	Revised version Patient Attitudes Towards Deprescribing
SCT	Social cognitive theory
TPB	Theory of planned behaviour
TRA	Protection motivation theory
TTM	Trans-Theoretical Model of behaviour change
WHO	World Health Organization

6. ETHICS

- *This protocol, any protocol amendments, informed consent form and other relevant documents (eg. recruitment advertisements) will be submitted to the Ethics Committee (EC) for formal approval to conduct the study. The decision of the EC concerning the conduct of the study will be made in writing to the sponsor. All correspondence with the Ethics Committee will be retained in the Investigator File.*
- *The study will be conducted in accordance with legal and regulatory requirements (Belgian law of 7 May 2004, Belgian law for Patient rights 22 August 2002, Private life GDPR 2018), as well as the Guidelines for Good Clinical Practice (International Conference on Harmonization 1996), and the last version of Declaration of Helsinki (World Medical Association).*
- *All subjects for this study will be provided a consent form describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. This consent form will be submitted with the protocol for review and approval by the EC. The formal consent of a subject, using the EC-approved consent form, will be obtained before that subject is submitted to any study procedure. This consent form must be signed by the subject or legally acceptable surrogate, and the investigator-designated research professional obtaining the consent. The written informed consent document should be prepared in the language of the potential patient population.*
- *The identity of the participant will remain kept confidential according to the General Data Protection Regulation of 27 April 2016 (in application on 25 May 2018), to the Belgian law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data and the Belgian patient's right law (22 August 2002). Personal data will be coded. Subjects will not be identified by name or in any other recognizable way in any of the records, results or publications related to the experiment.*

7. BIBLIOGRAPHIC REFERENCES

Prescribing medication is an essential dimension in the care of the older adults (i.e. people aged 60 or 65 and over, as per *World Population Ageing 2019: Highlights* (s. d.)), and the optimization of drug prescribing, has become an important public health issue, especially for the older adults (Spinewine et al., 2007). Even if, polypharmacy (i.e. five or more medications; (J. Reeve et al., 2022; Gabauer, 2020), may be appropriate in the treatment and prevention of different symptoms or disorders in older adults with multimorbidity (J. Reeve et al., 2022; Steinman, 2016; Spinewine et al., 2007), taking multiple medications may also be linked to a higher risk of medication-related problems. In fact, the aging process leads to physiological changes that can significantly alter both pharmacokinetics and pharmacodynamics (Pazan & Wehling, 2021). These age-related physiological changes can increase the risk of adverse drug events, and the inappropriate polypharmacy can contribute to drug-drug interaction, lower adherence to medication, significant costs to both the patient and the health care system, and also decrease the ability of people to perform activities of daily living, due to a functional decline, injurious falls, cognitive impairment, among others (O'Donnell & Ibrahim, 2022; Gabauer, 2020).

Therefore, it seems important to reflect, at different levels - micro, meso and macro, on the challenges related to the problematic polypharmacy, i.e. *"the use of multiple medicines on a long-term basis when the intended benefit of the medicines is not achieved, on the potential risks outweigh the intended benefits"* (J. Reeve et al., 2022). Indeed, this large-scale problem was recognized by the World Health Organization (WHO) that launched in March 2017 the third Global Patient Safety Challenge with the theme of medication without harm.

Deprescription, defined by Reeve et al. (2022) as *"a planned/ supervised process of dose reduction or the stopping of medicines that may be causing harm or conferring no additional benefit"*, can thus be a strategy, not only in the optimization of drug use in a context of polypharmacy, but also a strategy to revert the clinical and economic burden of polypharmacy (Reeve et al., 2022; Roux et al., 2022).

In reality, a systematic review and meta-analyses realized by Page et al. (2016), emphasized that this process of deprescribing to reduce polypharmacy is, not only feasible, but also safe. In addition, deprescribing seems to have some health benefits, and there are a trend to decrease mortality in the 65-80 years-old age group (Page et al., 2016).

Therefore, in this process of de-prescription, the patient, and even the informal caregivers, should have an active role in the health decisions that concern themselves (Chock et al., 2021; Baumgartner et al., 2020). Deprescription requires, in this way, a person-centered approach, with a shared decision-making process, and according to E. Reeve et al. (2018), some older patients are willing to be involved in this decision making process.

However, physicians report some patient reluctance or unwillingness to deprescribe, which is a very significant barrier to implementing deprescribing in clinical practice (E. Reeve et al., 2018). In fact, according to Parker et al. (2022), taking into account the patient and his impact in deprescribing, is an essential factor to understand and thus increase the effectiveness of interventions to reduce low-value care.

Therefore, as implementation deprescribing requires a complexes changes to established patters of behaviors (Scott et al., 2021), understanding the cognitive mechanisms underlying patient's and caregiver's behavior with respect to deprescribing, seems essential to improve the

collaborative work between the patient, or even the caregivers, and the health professionals, to achieve the best health outcomes for the patient (Parker et al., 2022; E. Reeve et al., 2013).
In reality, HBT provides a series of concepts deriving from social, cognitive and motivational psychology, that can be useful in understanding why people behave in certain ways in relation to their health (Gehlert & Ward, 2019). The most well-known and often-used theories are the Health belief Model (HBM; (Godin, 1991), the Theory of Planned Behavior (TPB; (Ajzen, 1991), as an extension of the Theory of Reasoned Action (TRA; (Ajzen & Madden, 1986), and the Protection Motivation theory (PMT; (Rogers, 1975). One major limitation of these models is that they actually "predict" behavioral intention, but they do not inform how to change health behaviors (Parker et al., 2022; Bandura, 2004, Godin, 1991).
Consequently, Bandura (2004) proposes a causal model, the Social Cognitive Theory (SCT), that *"offers both predictors and principles on how inform, enable, guide, and motivate people to adapt habits that promote health and reduce those that impair it"*. According to this theory, *"behavior, cognitive and other personal factors, and environmental events all operate as interacting determinants that influences each other bidirectionally"* (Bandura, 1988).
Moreover, given that behavior change involves processes that take place over time, the Trans-Theoretical Model of change (TTM; (Prochaska & DiClemente, 1983)) posits that health behavior change is a process that involves progression through a series of six stages of change: precontemplation, contemplation, preparation, action, maintenance, and termination (Prochaska & Velicer, 1997).
It is also interesting to note in Reeve et al.'s (2013) systematic review, that despite patients' ability to understand the risks and benefits associated with a certain behavior, especially about drug therapy, they showed limited ability to translate this information into decisions about whether or not the therapy is appropriate. This finding is even more striking among the elderly who often have a lack of knowledge about drug treatment and poor understanding of treatment aims, which consequently can be reflected in the inappropriate use of medicines (Parekh et al., 2018). Therefore, these elements refer to *Health Literacy* (HL), that can be defined as *"the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions"* (Nielsen-Bohlman et al., 2004 cit by Parekh et al., 2018), and that may be an important covariant to consider in the context of deprescription.

Screening Tools

In clinical practice, the existence of screening tools can be very useful, in this case to identify patients who will be more likely to respond well to therapeutic deprescription interventions (Turner et al., 2020). In reality, several tools have been developed and used, particularly in the identification of inappropriate drug use in the older patients, such as The Beers criteria (Beers, 1997) and Medication Appropriateness Index (Hanlon & Schmader, 2022). However, and despite its wide use, these tools do not provide guidance on how to stop inappropriate medication (E. Reeve, Shakib, et al., 2013).
In addition, the success of therapeutic deprescription will depend not only on medical factors, but also on patient factors. Therefore, being able to explore and objectively capture patients' beliefs and attitudes towards this therapeutic strategy seems essential (E. Reeve, Shakib, et al., 2013). Thus, other tools have been developed, including *The patients' attitudes towards deprescribing* (PATD) questionnaire, and its revised version questionnaire (rPATD; (E. Reeve

et al., 2016)), and Beliefs about Medicines Questionnaire (specific section) (BMQ-Specific) (Horne et al., 1999).

However, according to Turner et al. (2020) analyses, all 25 items found in the rPATD and BMQ-specific screening, only 8 were associated with deprescribing outcomes. In addition, these tools presents a low predictability validity for successful deprescribing (Chock et al., 2021; Turner et al., 2020), and an important gap between participants' intention and deprescribing behavior was also identified by Turner et al. (2020), with 86% of participants that are willing to deprescribe, but only 41% of participants successfully deprescribing their prescription. This significant gap and low predictive validity, can be explained by the fact that PATD and revised version was developed without a behavioral theory as a theoretical basis, whereas attitudes are a construct present in models of health behavior, such as the TPB (Ajzen & Madden, 1986). As a result, this questionnaire as well as the BMQ-specific questionnaires, do not take into account different critical domains that can be relevant to deprescribing, such as self-efficacy beliefs, outcome expectations, subjective norms, health goals, environmental barriers and enablers, among others (Linsky et al., 2015).

8. RATIONALE

The studied population in this study is twofold: older adults and informal caregivers.

Older adults

This study has a focus on particular population - older adult population. Advances in medicine have led to an increase in life expectancy, and a worldwide rise in the number of older people. As a result, several problems have also accompanied this increase, such as the growing number of chronic diseases and related polypharmacy, resulting in a significant burden not only for the older person, but also for healthcare systems (Pazan & Wehling, 2021).

Informal caregivers

In addition, the aging process can bring about different changes and disabilities in sensory, cognitive and physical functions, which may lead some older people to choose to involve family members or close friends in managing their health (Wolff & Boyd, 2015).

Hypothesis

According to Chock et al. (2021) and Turner et al. (2020) current tools, such as the BMQ and the widely used rPATD, have a number of limitations, particularly in terms of predictability validity for successful deprescribing. In addition, the rPATD items were developed without any theoretical basis in health behaviors, whereas attitudes are an important concept found, in particular, in the TPB (Ajzen & Madden, 1986). As a result, we hypothesis that the use of health behavioral constructs in the development of an assessment tool will have greater predictability validity on deprescribing behavior than that of existing tools.

9. OBJECTIVES AND GOALS OF THE STUDY

Primary objective:

To develop and validate a health behavior theory-based questionnaire to examine the older adults' and informal caregivers' determinants of deprescribing intention or behavior (with separate version for older adult and informal caregiver).

Secondary objectives:

- Establish the face and content validity of the questionnaire;
- Assess the psychometric properties of this new tool, by performing an exploratory factor analysis (EFA).

Expected benefits of the research

Despite the many benefits of taking medication, multimorbidity and the chronicity of certain health problems lead to multi-medication intake, which can entail major risks for the older people. Thus, deprescribing is an important dimension in the care of the older adults, and this study intends to provide a new instrument, developed on the basis of constructs from behavioral health theories, which is expected to be more accurate than those currently in use. This tool will thus be able to provide more information about the older adults' and their caregivers' views about deprescribing and also the socio-cognitive factors that can impact their willingness to engage in deprescribing behavior. Consequently, this information could be useful in the development of interventions aimed at medication deprescribing, with a patient-centered or family-centered deprescribing approach.

STUDY DESIGN AND METHODOLOGY APPLIED

9.1. Design

Type of study

Questionnaire development and validation – older adult and informal caregiver version

Study configuration

The initial questionnaire was developed considering the results of a previous systematic review (article currently being written), which was intended to identify (concepts included in) behavioral health theories (HBTs) that explain older adults' and informal caregivers' deprescribing intention and/or their actual deprescribing behavior. This systematic review, reveled several main dimensions, such as goals intention to deprescribe, perceived risks about medication, self-efficacy towards deprescribing, subjective norms, social support to deprescribe, and finally opportunities for deprescribing. This systematic review, also showed that attitudes was already widely investigated, indeed four systematic reviews and two meta-analysis were already performed, synthesizing studies that have used PATD and the revised version (Seewoodharry et al., 2022; Oktora et al., 2022; Chock et al., 2021; Weir et al., 2021). As a result, the items of this initial questionnaire were developed according to the dimensions found in the systematic review, the main results of the systematic review focused on the rPATD and the Beliefs about Medicines questionnaire (BMQ), since a predictor of risk perception was beliefs about medication (Martin et al., 2013).

The initial version for informal caregivers was developed by modifying the wording of the items, in the version for the older adults, adapting them for informal caregivers.

Another two questionnaires will be used in this study: one that measure health literacy (HLS19_Q12; (Pelikan et al., 2022)) and another one that assess the locus of control (MHLC; (Wallston et al., 1978)). The previous systematic review reveled that the HL was positively associated with the willingness to deprescribe (Gillespie et al., 2019). The HLS19_Q12 is thus the questionnaire that will be used in this study. This instrument was built on the conceptual framework and definition of comprehensive, general HL developed in the HLS_EU (Pelikan et al., 2022). Indeed, the concept-based in the development of HLS_EU refers to *"... people's knowledge, motivation, and competencies to access, understand, appraise and apply information to form judgements and take decisions in terms of healthcare, disease prevention and health promotion to improve quality of life during the life course"* (Sørensen K et al., 2012 cit by (Pelikan et al., 2022).

In addition, the locus of control was also identified in one study, in the previous systematic review, as having an impact on deprescribing behavior (Elsesser & Sartory, 1998). As a result, the Multidimensional Health locus of control scale (MHLC; (Wallston et al., 1978)) will be used. According to Lachman (1986) the multidimensional measurement is desirable for the older people, because *"it allows for the possibility of differential change trajectories across dimensions"* (Gurin & Brim, 1084 cit by Lachman, 1986), as in the aging process older people may become more sensitive to the external power or chance, but without changing one's sense of internal control (Lachman, 1986).

Study design

The development and validation of the questionnaire comprise 4 steps:

1. **Item Development process**

The conceptualization of the concepts used in the questionnaire was based on the results of the systematic review carried out previously. The items were built in relation to the most relevant constructs and predictors identified in the results of the systematic review, and some items from two different questionnaires (rPATD and BMQ) were also used to assess the components of some constructs, such as attitudes and perceived risk. The dimensions importance, in a first step were identified by discussion with the promotor in relation to the systematic review results. The questionnaire and items format were also discussed with the promotor, and a statistician from SMCS.

Some considerations have been taken into account in the item construction: *"Statements should be simple and short as possible, and the language used should be familiar to target respondents… Items should address only a single issue… Leading questions should be avoided, as they may bias responses. Items that all respondents would answer similarly should not be used, as they will generate little variance"* (Hinkin, 1998). In addition, items related to deprescribing behavior were regrouped and separated from those related to medication use.

2. **Preliminary pilot testing**

All piloting process will follow an iterative approach, allowing adjustments to be made throughout the exchanges between the various stakeholders involved in this process.

a. Prior to the pre-test, the questionnaire will be distributed to 5 colleagues on the research team to check all the initial items and adjust them, if necessary.

b. Then, "cognitive pre-test" will be performed with 5 older adults and 5 informal caregivers to check the linguistic and analytical construction of the items, through respondent

understanding of the items in the questionnaire. This first test will be performed by qualitative methodology, more precisely structured interviews. Respondents will be encouraged to express their thinking aloud when answering each item. After this first test, items that caused comprehension problems will be discussed with the research team and then they will be adjusted or eliminated. The results of this first test lead to a first draft of the questionnaire to the older adults and to the informal caregivers.

c. In the following step, the item development and questionnaire validation will include a first round with healthcare professionals, and a second round with older adults and informal caregivers. This phase will assess the face and content validity. Different techniques can be used to assess content validity, but in this study we will use the one proposed by Lawshe (1975), the Content validity ratio (CVR), once it has also been used in other studies such as for the validation of the rPATD (E. Reeve et al., 2016).

i. Healthcare professionals

According to the principle of purposive sampling, 8 health professionals: 2 geriatricians, 2 general practitioners (GP), 2 pharmacists, and 2 nurses, will be enrolled in this study to rate on a Likert-scale the appropriateness of having each item in the questionnaire.

For improving the questionnaire, participants will also be encouraged to make comments and suggestions.

One focus group (FG) will be then organized to discuss the results from this second test, and a second draft can be developed, after discussing the results with the research team and before offering it to older adults and their informal caregivers.

As regards the FG, it's essentially a small group of people, between 6 and 16, who come together to discuss a particular and common subject (Kohn & Christiaens, 2012). Consequently, one group with health care professionals will be composed of at least 6 participants who have showed an interest in participating in the discussion (question at the end of the questionnaire). The focus group will be moderated by the co-investigator and will take place at a location to be agreed with the participants.

ii. Older adults and informal caregivers

As for the healthcare professionals, a convenience sample of 10 older adults, and 10 informal caregivers, will be asked to provide individual feedback on the questionnaire items. One FG, with older adults and informal caregivers will be organized to discuss the results of the self-administered questionnaire. The group will be composed of at least 6 participants (3 older adults and 3 informal caregivers) who have shown an interest in participating in the discussion (question at the end of the questionnaire). A third version of the questionnaire will be obtained after discussion the results with research team.

3. Pre-test of the questionnaire – older adult and informal caregiver version

Once the final version of the questionnaire developed, it will be administered to a small group of participants, generally 10% of the sample size required to perform an EFA (Aithal & Aithal, 2020). It will be asked to the older adults and to the informal caregivers to complete the questionnaire and to provide any comments about the way items have been written and on items comprehension. This pilot study will help to assess the clarity of the items and to remove irrelevant items.

In this validation step will also be administered the HLS19_Q12 and MHLCS.

4. **Validation of the questionnaire** – older adult and informal caregiver version

The final item selection process will incorporate the results of the different qualitative analyses (interviews and FG) and quantitative analyses of the field trial data. This final version of the questionnaire will be then applied to a large sample size of older adults and informal caregiver for reliability validation.

This validity process *"... refers to the degree to which evidence and theory support the interpretations of test scores for proposed uses of a test. Validity is, therefore, the most fundamental consideration in developing and evaluating tests"* (AERA, APA, & NCME, 2014 cit by Clark & Watson, 2019). As a result, during this phase, a construct validity will be carried out, which is related to the *"evaluation of the extent to which a measure assesses the construct it is deemed to measure"* (Strauss & Smith, 2009). The internal consistency will be also calculated, as it reflects *"the extent to which the questionnaire items are inter-correlated, or whether they are consistent in measurement of the same construct"* (Tsang et al., 2017). Finally, a test-retest reliability will be performed, by repeating the administration of the same questionnaire with a small sample of participants (20 older adults and 20 informal caregivers) who have already completed the questionnaire. This process will ensure the consistency of questionnaire items responses across repeated administration (Tsang et al., 2017).

The two additional questionnaires (HLS19_Q12 and MHLCS) will be administered to all participants (older adults and informal caregivers) in this final stage of the questionnaire validation process.

Expected duration of subject participation

Participants will be included throughout the questionnaire development and validation process, which will begin as soon as the ethics committee's opinion is received, and will continue until the sample size required for validation of the questionnaire is reached, in the final phase. The whole process is expected to take around 12 months.

Planned timetable

Activities/ Months	**2023**										**2024**						
	06	07	08	09	10		11		12		01	02	03	04	05	06	07
				15d	15d	15d	15d	15d	15d	15d							
Questionnaire development																	
Ethics committee																	
Cognitive pre-test with OA and IC																	
Round with HCP																	
FG with HCP																	
Round with OA and IC																	
FG with OA and IC																	
Questionnaire validation																	

HCP: Healthcare professionals; FG: focus group; OA: older adults; IC: informal caregivers

Method for data collection

The questionnaire begins with a short introduction covering the importance of the study, its objectives, anonymity and the non-obligation to participate in the study and withdraw if desired. Consent will be signed before starting to fill in the questionnaire. The questionnaire initially asks 3 questions to determine participant eligibility, and the initial draft of the questionnaire consists of 3 main parts:

1. First section with questions relating to the socio-demographic and clinical characteristics of the participants. There are 5 basic demographic questions related to age, sex, education, relationship status, residence (at home, NH, …). Three additional questions are included in this section to: (1) assess how the person feels about his or her health or that of the care recipient, on a Likert scale ranging from 1 "Poor" to 5 "Excellent"; (2) to know how many different medications (including those not prescribed by the doctor) the older person/care recipient takes per day; (3) to know if the person or the care recipient has ever tried, in the past, to reduce or stop some of the drugs in their usual treatment; (4) to know if the person/ informal caregiver are willing to deprescribe; (5) to know if the person/ care recipient is currently in the process of deprescribing at least one of the medication he or she is currently taking.
2. Second section with 58 questions for older adult questionnaire version and 55 questions for the informal caregiver version on factors that may be potential obstacles or facilitators to deprescribing behavior. Each item is rate on a Likert scale going from 1 "strongly disagree" to 5 "strongly agree".

9.2. Third section with 3 open-ended questions for participants to comment on the questionnaire format, factors that have not been addressed and items that may not be relevant. An additional question is added to this first draft to identify participants interested in participating in the FG.Description of the population

Older Adult population

- Be at least 60 years old : different ways of defining the older people exist, but in statistical terms, the older people are often classified above a certain age threshold (European Commission. Statistical Office of the European Union., 2020). For the purposes of this study, we adopt the definition given by the United Nations in its report called *World Population Ageing 2019: Highlights* (s. d.), that older people are those aged 60 or 65 years or older.

- Take 5 or more medications daily: the ageing process is often accompanied by an increasing burden of chronic illness, and consequently by chronic medication use that can lead to polypharmacy, defined as taking 5 or more medications (Nordin Olsson et al., 2011). In turn, polypharmacy can be considered as the most obvious sign of risks in medication treatment (Nordin Olsson et al., 2011), and potentially inappropriate medication (PIM) that include medication and medication combination, should be avoided in this population due the higher risk of causing more harm than benefit for the user, in particular, an increase mortality (Muhlack et al., 2017).

Informal caregivers

- Spouse, family member or closer friend: in this study informal caregiver refers to a family member, a friend that provide care or support to a dependent older person with physical or cognitive functions declines. The relationship between the informal caregiver and the care recipient is based on solidarity, and so *"based on mutual help and moral obligation within families and social networks. Informal caregivers' work can be unpaid or remunerated" in some way*" (Abouzaid et al., 2014). Therefore, in this study those who provided informal care are: (a) working-age adults who care for older parents with disabilities, family members, neighbors or friends; (b) people of retirement age or older who care for their partner, family members, neighbors or friends

In addition, the role of the informal caregiver may vary depending on the older person's disability, but also according to their own characteristics. However, in the ambulatory setting, medication management has been identified as one of the most important informal caregivers' role, and good medication management *"contributes to improve health outcomes and reduce institutionalizations for the care recipient"* (Gillespie et al., 2014). As a result, informal caregivers should be involved in the deprescribing decision and process (E. Reeve et al., 2016).

Number of participants expected

Healthcare professionals	**n=8**			
	Questionnaire self-administration: 2 geriatricians, 2 GP, 2 pharmacists, and 2 nurses			
Older Adults	**n=345**			
	Cognitive pre-test: n=5	Questionnaire self-administration: n=10	Pre-test: n= 30	Validation: n=300
Informal caregivers	**n=345**			
	Cognitive pre-test: n=5	Questionnaire self-administration: n=10	Pre-test: n= 30	Validation: n=300

9.3. Strategies for recruiting participants

Health care professionals

For the recruitment of healthcare professionals, several organizations will be contacted, more specifically:

- General practitioners: « Centre académique de médecine général » - CAMG; ASBL « Collège de Médecine Générale de Belgique francophone » ;
- Specialist physician: Belgian Young geriatricians – BYG and the Belgian Society of gerontology and geriatrics – BSGG;
- Pharmacists: "Centre académique de soins pharmaceutiques » - CASP and the Belgian pharmaceutical association – APB

- Nurses: convenience recruitment through contact with a number of nursing home and homecare associations.

Different recruitment channels are envisaged to ensure that the healthcare professionals who will be recruited have no relationship with the researcher and/or the sponsor of this study.

Older adults

Initially, convenience recruitment will be carried out for the "cognitive pre-test", and for the questionnaire self-administration and FG. The French-speaking federation of patient and family associations- LUSS, and ASBL "Aidants proches", will be contacted to help recruit participants. Then, older adults in ambulatory setting will be recruited through community pharmacies and GP. Contacts will be made with a large number of community pharmacies and also with GP in private practice and in "Maison Médicale" practices, in Brussels and Wallonia. Eligible patients will receive from pharmacists and GPs an envelope containing the information form, consent form and questionnaire, as well as a stamped envelope for returning the questionnaire and signed consent form.

In addition, day centers for older adults will be contacted, as well as organizations and social-health services and "Résidence Service". For Brussels, Iriscare provides a list of available day centers, and senior.irisnet provides a list of homecare organizations. For Wallonia, AVIC provides a list of day centers to contact, as well as a list with homecare organizations. For the older adults who are eligible and agree to participate, a member of staff or the researcher will inform residents about the study, request the signature of informed consent and, if necessary, help in completing the questionnaire. For participants who are unable to take part, their informal caregivers will be asked if they are willing to participate (informal caregiver version of the questionnaire).

For the NH participants, a convenience sample of NH, in Brussels and Wallonia, will be contacted for participation. As for the day-care centers, the researcher or a NH staff member will inform residents about the study, request the assignment of consent and, if necessary, help in completing the questionnaire.

Informal Caregivers:

As with the recruitment of seniors, LUSS and ASBL "Aidants proches" will be contacted to help recruit participants. Pharmacists and GPs will also be informed of the informal caregiver version of the questionnaire, and if eligible, will give to the caregiver an envelope with information form, the consent form, and the questionnaire (informal caregiver version) together with a stamped envelope to return the questionnaire and the signed consent form.

For residents in NH, or in a day-care center, or for those at home but unable to fill in the questionnaire and who have a close caregiver, the staff member of the different teams will provide the information and give all the necessary documents, as well as the questionnaire, to the close caregivers who agree to take part in the study.

9.4. Inclusion criteria

Older adult participants will be eligible for this study if they satisfied the following criteria:

- Age 60 years or older;
- Taking at least 5 medications daily;
- Having at least one chronic condition.

Informal caregiver participants will be eligible for this study if:

- They self-identified as a caregiver (defined as having any role in a family member or friend's management of health and/ or medication management) of an older adult who has 60 years old or older, that are taking at least 5 medications daily;
- The care recipient lived in the community (at home with or without the caregiver) or in a NH.

9.5. Exclusion criteria

Older adult participants will be excluded from this study if they meet any of the following criteria:

- Suffering from psychiatric trouble;
- Past or present drug or alcohol dependency;
- Having a terminal illness;
- Inability to complete a written questionnaire in French due to a functional or cognitive impairment;
- Inability to understand and express oneself in French.

Informal caregiver participant will be excluded from this study if they meet any of the following criteria:

- Caregiver age under 18 years old;
- Caregivers who are paid for the care they provide;
- Caregiver inability to give consent and complete a written questionnaire in French;
- Caregiver inability to understand and speak in French.

9.6. Withdrawal

Not applicable

9.7. Protocol Deviations

Any significant deviations from the study inclusion or exclusion criteria, study conduct, patient management or evaluation will be described and justified in the final report and communicated to the Ethics Committee, as appropriate.

9.8. Data Management Responsibilities

The questionnaire for the older adults will be either a paper version for self-administration, or completed with the help of the researcher or a member of the NH or day-care center staff. However, considering the growing development of IT tools for all age categories, and despite the fact that the older people are slower in adopting new technologies compared with the young, there is a proportion of this population that uses new information and communication technologies (Yap et al., 2022). So, a questionnaire will also be available online, and distributed through older adults' association above for recruitment purposes, and personal or professional networks, in Belgium.

The questionnaire for informal caregivers will also have both a paper and an online version, distributed by the caregiver associations and also by personal or professional networks, in Belgium.

Both versions of the questionnaire will be distributed using Qualtrics (UCL license) - a cloud-based platform for creating and distributing web-based surveys.

9.9. Data breach

Before taking part in this study, participants will be informed how, by whom and for which purpose they are being asked to be involved. This information will be given in writing in an information sheet together with the consent form (Appendix).

Qualitative methodology

For the first qualitative phase of the questionnaire's development, anonymity of all participants (healthcare professionals, older adults and informal caregivers) will be ensured by assigning an identifier code when analyzing comments from the questionnaire's self-administration and when transcribing and analyzing the FG. Also, to ensure that participants are not identified, but to be able to re-contact them, in particular for FG planning, any information likely to reveal the identity of participants (names) will be put in a separate document, secured by a password and stored offline on the hard. The questionnaires' comments and transcribed FG will also be stored offline and password-protected for 20 years at the 'Service des Archives' from the UCLouvain.. This procedure will be also explained to the participants, written and orally.

Quantitative methodology

In the quantitative phase of questionnaire validation (older adult and caregiver version), participants (older adults and informal caregivers) will be informed in writing, via an information sheet attached to the consent form, of how, by whom and for what purpose they are being asked to participate. In addition, in specific settings: ambulatory setting – day-care and home care and in NH setting, the information will also be communicated orally to the older adults, together with the information sheet and the consent form. It will be explained orally and in writing that participants will be free to choose whether or not to take part in the study, with no implications for the quality of care they receive, or for the relationship between patient/ informal caregiver and healthcare professional. They will also be free to withdraw from the study at any time without justification.

For those who agree to participate, anonymity will be ensured by the allocation of an identifier code. All information likely to identify participants, such as name, date of birth or address, will not be requested. In this study, general information, such as age category, gender, place of residence (at home, accompanied or alone, in a NH), marital status and level of education will be requested.

In this study, participants will not be asked about sensitive information concerning the health of the older adult, or about information contained in patient records (e.g. biometric data, hospital information, medical photographs, biological traits, genetical material, among other sensitive information), and no patient records will be consulted. Other types of sensitive information, such as those revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, sexual orientation or activity will not be investigated. This study will focus on questions relating to the number of medications taken by the person or care recipient, as well as their perception of their (or the care recipient's) health status, medication deprescription and medication intake. All the data to be collected are based on a theoretical

framework derived from a systematic literature review, and are aimed at being adequate and relevant to the development and validation of the questionnaire.

Qualtrics is a secure web application that will be use to encoded paper questionnaires, and also for data capture from the online questionnaires. Only the users that need to access the data (the research team) will be allowed to do so, and paper questionnaires will be destroyed once they have been transcribed into Qualtrics.

No data transfer is planned in this study, either within or outside the European Union.

In the event of unintended disclosure of data, no negative effects are expected for participants. In addition, any protocol breaches will be immediately (within 7 days) reported by the investigator, in accordance with the investigators, to the Ethical Committee.

The Sponsor or designee must report to ethics committee, serious data breaches : transgressions against the study protocol or the regulation that are likely to significantly affect the safety and rights of a subject or the reliability and robustness of the data generated in the study.

9.10. Data Analysis

9.10.1. Qualitative Analysis

In the early stages of questionnaire development and validation – face and content validity, it seemed appropriate to seek the opinions and comments of healthcare professionals with expertise in the care of the older people and who are aware of the problem of polypharmacy and the importance of medication deprescription, as well as our target population – older adults and informal caregivers. In this respect, a qualitative methodology is appropriate for understanding the needs of users and care providers (Kohn & Christiaens, 2012). For the data analysis, the open-ended questionnaire responses concerning comments will be analyzed for common or contradictory information, which will be used to construct the guide for the FG.
Full transcriptions of the FGs will be performed and an analysis of the corpus will be carried out by deductively identifying the units of analysis, which will be used for adjusting or eliminating items from the questionnaire.

9.10.2. Statistical Analysis

To assess the psychometric properties of the questionnaire, an EFA will be performed. The aim of this study is to develop and validate a new measurement instrument, which is why we will use an exploratory method, as no a priori structure is known about the linear relationships between items and factors. (McCoach et al., 2013). Thus, using the EFA it will be possible to reduce data by exploring *"... the dimensionality of an instrument by finding the smallest number of interpretable factors needed to explain the correlations among set of items"* (McCoach et al., 2013).

Sample Size

According to Yong & Pearce (2013), EFA performs better with a larger sample size, as it reduce the error in the data. However, no formal sample size calculation is available for EFA, some authors recommend at least 200 participants (McCoach et al., 2013), while others put the targeted figure at 300 (Yong & Pearce, 2013). So, in this study, we are targeting a sample of 300 older adults and 300 informal caregivers. For the test-retest reliability, a sample size of 20

older adults, and 20 informal caregivers will be selected, as was used for rPATD validation (E. Reeve et al., 2016) and rPATD version for BZD (Pétein et al., 2023).

As described earlier, this study will include an heterogeneous sample (recruitment will be carried out in various structures in Brussels and Wallonia) to minimize the influence of variance and factor loading, which *"give us an idea about how much the variable has contributed to the factor… they represent the strength of the correlation between the variable and the factor"* (Kline, 1994 cit by Yong & Pearce, 2013).

Psychometric proprieties of the questionnaire

The appropriateness of the data factor analysis, considered *"to be a variable describing how much an individual would score on a factor"* (Yong & Pearce, 2013), will be assessed using the Kaiser-Meyers-Olkin test and Bartlett's test of sphericity. Factors will be extracted using the Principal Axis Factoring, that is based on the notion *"that all variables belong to the first group and when the factor is extracted, a residual matrix is calculated. Factors are then extracted successively until there is a large enough of variance accounted for in the correlation matrix"* (Tucker & MacCallum, 1997 cit by Yong & Pearce, 2013). In addition, for a better interpretation of the factors, a rotation will be performed, more precisely an oblique rotation (Yong & Pearce, 2013). The number of factors to be retained will be determined using the Kaiser-Guttman criterion (retaining all factors that are above the eigenvalue of 1) and the scree test (retaining all factors that are above the point of inflexion in the scree plot). Loadings above 0.30 will be considered as significant, as *"anything lower would suggest a really weak relationship between the variables"* (Tabachnic & Fidell, 2007 cit by Yong & Pearce, 2013).

Another essential step in the creation of a questionnaire is to gather evidence of the score's reliability (E. Reeve et al., 2016). In reality, score reliability *"is an indication of the consistency, stability, or precision of scores"* (McCoach et al., 2013). Consequently, reliability focus on two types of measurement: internal consistency that estimate a *"measurement error within the set of questions"* (McCoach et al., 2013) and test-retest reliability estimates, that is a measurement error across two or more instrument administration (McCoach et al., 2013).

The most commonly used estimated of internal consistency is Cronbach's coefficient alpha (α; (McCoach et al., 2013)). Nevertheless, α is predicted on several assumptions, that are not always respected (Trizano-Hermosilla & Alvarado, 2016; McCoach et al., 2013), which is why the omega coefficient (ω; (McDonald, 1999)) will also be used, as an alternative to α (Doval, 2023; Trizano-Hermosilla & Alvarado, 2016). In reality, a number of researchers showed that ω is a more sensible index, with lower risk of over- or underestimating reliability (Dunn et al., 2014). Therefore, the reliability coefficient range between 0 and 1, and a value above 0.7 will be considered as good internal consistency, while a value above 0.90 will be considered as excellent (Koo & Li, 2016).

According to Koo & Li (2016) *"A more desirable measure of reliability should reflect both degree of correlation and agreement between measurements"*, that's why the intraclass correlation coefficient (ICC) will be used to evaluate test-retest reliability at the factor level, and linear-weighted Cohen's Kappa and percent agreement at the individual item level. These measurements have been used to validate other instruments such as rPATD (E. Reeve et al., 2016) and the rPATD version for BZDs (Pétein et al., 2023). The ICC classified the reliability

as poor (<0.50), moderate (0.50-0.75), good (0.75-0.90) and excellent (>0.90) (Koo & Li, 2016). The Cohen's Kappa nomenclature classify the strength of agreement also as poor (<0.00), slight (0.00-0.20), fair (0.21-0.40), moderate (0.41-0.60), substantial (0.61-0.80) and almost perfect (0.81-1.00) (Landis & Koch, 1977).

All numerical variables will be described using means, medians and standard deviation, whereas all categorical variables will be described using frequencies and proportion. A logistic regression analysis will be performed to better understand the association of items from the questionnaire and intention, or actual deprescribing behavior. The moderating influence of HL and locus of control on the effect of the determinants on deprescribing intention or behavior will be checked via moderation analysis using bootstrapping. Statistical analysis will be conducted using SPSS Statistics version 1.0.0.1406, and a type I error rate of <0.05 will be considered significant.

9.11. Protocol Amendements

If amendments to the protocol (modifying sense or objectives or modifying the study procedures) turn out to be necessary, they will be subjected at first opinion of the promoter of the study. After agreement by the promoter, these amendments will then be submitted to the opinion of the Ethic Committee having examined the initial protocol.

10. FINANCE AND INSURANCE

This study is part of WP2 of the Di-Prescribe project, with ARC funding.

As part of this project, a budget has been set aside for stakeholder involvement. As it is planned to carry out FG with healthcare professionals, older adults and informal caregivers, a compensation of 50€ per person and per meeting will be granted. The budget also includes a travel allowance for participants. In addition to the involvement of stakeholders, a cost will be incurred for the purchase of stamps and envelopes for the return of paper questionnaires. This cost will be covered by the budget allocated for this purpose by ARC project.

The experimentation is covered under the Belgian Law of May 7, 2004 by a no-fault insurance (type of coverage: liability insurance).

Policy holder:
UCLouvain
Place de l'Université 1
1348 Louvain-la-Neuve

Issuer of the certificate of insurance:
MS Amlin Insurance SE
Boulevard du Roi Albert II, 37
1030 Brussels
N° de police : LXX111372

11. END OF STUDY

The study end date is the date of the last returned questionnaire, which will be required to reach the sample size estimation. A maximum of one year is planned to complete this study, including recruitment, data collection, data analysis and preparation of the publication.

12. DISSEMINATION OF RESULTS AND PUBLICATION POLICY

The progress and results of this study will be discussed with the Di-Prescribe research team. The protocol and final results will be presented at seminars scheduled as part of the doctoral program. At the end of the study, a scientific publication will be written by the co-investigator (Sara Alves Jorge) under the supervision of the sponsor representative and Prof Van den Broucke. A paper will also be written for publication in a peer-journal. Acknowledgements will be made to all those who will make this work possible, including healthcare professionals, the different institutions and organizations that will be contacted, as well as the older adults and informal caregivers who will take part in the study. In addition, some people who will be indirectly involved, in particular by giving support and guidance, will also be recognized.

13. ARCHIVING

At the end of the study, the paper data will be stored at the 'Service des Archives' from the UCLouvain for as long as dictated by local Ethical Committee and Institutional regulations. Data to be kept at least 20 years after the trial termination according to the Belgian legislation: RD 18 May 2006 art.24

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15. APPENDIX

- Patient information and consent form
- Questionnaires – older adult and informal caregiver version