Elderly Patients' Perspectives on the Acceptability of Deprescribing Medicines: A Qualitative Study Protocol

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Abstract

The ageing population has resulted in an increase in multimorbidity and polypharmacy, and subsequently the complexity of optimising elderly patients' medicines. The need for deprescribing can arise from factors such as increased susceptibility to adverse effects of medicines in older age, due to functional and cognitive changes, which increases elderly people's risk of harm. Previous questionnaire-survey-based research suggests that patients tend not to disagree with deprescribing, but qualitative research on patients' perspectives on deprescribing appears sparse and focused on specific conditions, circumstances (e.g., terminal illness) or medicines. Further exploration of this area is therefore important for health professionals, and greater understanding in particular is needed about elderly patients' perspectives on the acceptability of deprescribing and how best to conduct deprescribing consultations. This study aims to explore these issues, with an approach informed by the Theoretical Framework of Acceptability (TFA). Semi-structured, audio-recorded interviews will therefore be undertaken with a purposive sample of approximately 20 hospital in-patients who are ≥65years of age, prescribed at least one regular medicine and have multimorbidities and/or frailty. Two acute Trusts were identified through existing networks where patients will be identified by the ward pharmacist and recruited to the study by the researcher. Due to the nature of the discussion and the potential vulnerable nature of participants, a distress protocol has been created to support management of any distress or fatigue that may occur. The TFA has been used so far to develop the study objectives and interview guide topics. The interview guide has been structured into five broad topics, which will cover the constructs of the TFA. Interview recordings will be transcribed verbatim and analysed using the Framework Analysis technique, informed by the TFA.

Keywords

deprescribing, elderly, medicines

Introduction

Due to increasing life expectancy, health conditions (morbidities) and polypharmacy (defined here as *"five or more medicines daily"* (Masnoon et al., 2017)), optimising elderly patients' medicines has become more complex (Zwijsen et al., 2016). Multimorbidity (defined as *"the presence of two or more chronic conditions"* (Abebe et al., 2020)) increases the likelihood of polypharmacy and the likelihood of medicines being used inappropriately, which can lead to patient harm (Salahudeen, 2018). Up to 6.5% of hospital admissions have been reported to be related to Adverse Drug Reactions (ADRs), with up to 72% of these being deemed avoidable (Pirmohamed et al., 2004). Regular medicines reviews may allow for identification of these prior to a hospital admission (Ognibene et al., 2018).

Elderly patients are more susceptible to ADRs from polypharmacy and also from pharmacokinetic/pharmacodynamic and functional/cognitive changes with increasing age (Silva et al., 2015). The World Health Organisation (WHO) specifies

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that an elderly person would be defined as being of "*…a chronological age of 65years old or older…*" (World Health Organization, 2010). However, it is also recognised that people can age biologically at varying rates and that frailty has more impact on an individual's requirement for support (NHS England, 2017). Frailty can be defined as; "*a distinctive health state related to the ageing process in which multiple body systems gradually lose their in-built reserves*", therefore it is important to consider a patient's age in conjunction with their frailty status (Turner, 2014). In this specific group of patients, it is important to ensure that the risk versus benefit of medicines is regularly reviewed and deprescribing should be considered where the risk begins to outweigh benefit (Silva et al., 2015). Deprescribing can be defined as "*the process of withdrawal of an inappropriate medicine, supervised by a health care professional with the goal of managing polypharmacy and improving outcomes*" (Reeve, Emily, Gnjidic, Long, & Hilmer, 2015).

There have been numerous studies that used the validated Patient Attitudes Towards Deprescribing (PATD) questionnaire and the revised PATD (rPATD) (Galazzi et al., 2016; Kalogianis et al., 2016; Kua et al., 2019; Ng et al., 2017; Reeve et al., 2013; Scott et al., 2019; Sirois et al., 2017). Most of these studies found that patients tended not to disagree with deprescribing, (Kalogianis et al., 2016; Ng et al., 2017; Qi et al., 2015; Reeve et al., 2019; Sirois et al., 2017) and one PATD study in Singapore reported that a large number of patients did not want to be involved in the decisions around their medicines (Kua et al., 2019). However, whilst using questionnaires allows for a large data set to be obtained, these questionnaires use fixed response Likert scales to ascertain patients' (dis)agreement with specific statements, which do not allow for them to qualify or elaborate on responses or give assurance that they have fully understood the statement. Similarly, respondents are not able to say anything about related issues that may be important to them. As such, the use of the PATD and rPATD do not allow for the capture of information about issues such as whether patients may be more willing for some medicines to be deprescribed than others, for example, medicines for symptomatic relief over preventative medicines (Reeve, E. et al., 2019). A broad and in-depth understanding of patients' views about these and other issues around deprescribing is best explored using qualitative methods.

Qualitative research exploring elderly patients' views about deprescribing is sparse (Gilworth et al., 2019; Scott et al., 2020; Todd et al., 2017), particularly in the UK; the UK studies that have been conducted have focused on patients with specific conditions or circumstances (e.g. terminal care) or categories of medicines (Gilworth et al., 2019; Todd et al., 2016). Since such patients may well not have the same perceptions about the acceptability of deprescribing as elderly patients more widely, exploring elderly patients' perspectives on this is an important but under-researched area. Similarly, previous research has not explored elderly patients' perspectives on how consultations about deprescribing should be optimally conducted by health professionals to support patient-centred care. This study therefore aims to take a qualitative approach to explore these issues.

Methods

Study Design

This study is taking a broadly constructivist and theoretically informed qualitative approach. Semi-structured interviews were chosen for this project on the basis of being well suited to explore the breadth and depth of individual people's perspectives. The Theoretical Framework of Acceptability (TFA) (Sekhon et al., 2017) was used to inform this study on the basis of it having been developed for assessing how acceptable recipients find healthcare interventions and in this study deprescribing is considered to be an intervention. There are seven component constructs in the TFA: affective attitude, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness and self-efficacy. This guided the development of the interview guide and will inform the analysis of the data.

Patient and Public Involvement and Engagement (PPIE) was sought about the need and scope of the proposed project, the suitability of the wording of the Participant Information Sheet, consent form and the interview guide, as well as the suitability of the intended approach to participant recruitment.

In view of the vulnerability of the patient cohort, it was important to recognise the potential for fatigue or distress in patients and therefore to manage this, a distress protocol was developed from relevant literature (Draucker et al., 2009; Haigh & Witham, 2015). This outlines the steps that should be taken if a participant becomes tired, upset or distressed during the interview (Figures 1 and 2).

Eligibility Criteria

Inclusion criteria
- Consenting hospital in-patients aged 65 years or above AND taking at least one regular medicine AND with multimorbidity and/or frailty

Exclusion criteria

- Lack of mental capacity*
- Severe Cognitive impairment*
- Unable to speak English
- With Infectious COVID-19

*As assessed by the researcher checking the patient's medical notes

Sampling

A purposive sampling approach will be used, with the relevant participant characteristics being described in the inclusion

criteria above. Due to the nature of the population (elderly and unwell, with cognitive impairment being common) (Rait et al., 2005) the number of patients meeting the inclusion criteria may be low. This means that the researcher may need to screen a lot of patients to identify those who are eligible to participate (Kara, 2017).

Size of Sample

We will continue interviewing until thematic saturation is deemed to have been reached, which will be when no new themes relating to the broad topics in the interview guide are identified from the interviews. As all the interviews are to be conducted by one researcher, this researcher will note the point of absence of new themes from interviews and chart the emergence of themes through an interim analysis to check. A subsequent two or three interviews will then be conducted and if no new themes emerge from these interviews, then no further interviews will be conducted. From experience, we anticipate the likely number of participants to be around 20 participants on the basis of the relatively specific focus of the broad topics of interest.

Study Setting

The study will be conducted at two acute NHS Trusts, identified through existing professional networks as having elderly care wards typical of routine secondary care services in the UK. This will support the identification of patients who meet the eligibility criteria and the likely transferability of findings in the identified group of patients.

Recruitment

Participants potentially meeting the inclusion criteria will be identified to the researcher by a ward-based pharmacist (working as part of the patient's clinical team). The pharmacist will provide verbal information and copies of the participant information sheet and consent form to the patient. They will be given a minimum of 24 hours to read through all the information and discuss with family/friends should they wish to do so.

The researcher will then ensure that the patient meets the inclusion/exclusion criteria. The researcher will ask the patient if they have any questions and/or clarify any information that is required. If the patient wishes to take part in the study, the researcher will take informed consent from the patient and ask the patient to sign the consent form.

Data Collection

The interview guide has been developed on the basis of the aims and objectives of the study, the TFA (Sekhon et al., 2017) and concepts identified in existing questionnaires and guides from reviewing the literature (Linsky et al., 2019; Reeve, Emily, Low, & Hilmer, 2016; Reeve, Emily et al., 2018). The main areas discussed have been summarised in Table 1. The process of interviewing involves asking open, non-leading questions from the interview guide and then depending on participants' responses, further probing questions to clarify points made or explore issues further. The topics of interest to be explored in interviews with participants in this study are not of an overly sensitive, personal or upsetting nature, but it is possible that participants may begin to feel tired and/or distressed during the interview. Therefore, if this occurs the distress protocol will be followed (shown in Figures 1 and 2).

Data Analysis

Interviews will be audio-recorded and transcribed verbatim, with silences, gesticulations or other non-verbal expressions of emotion recorded in square brackets. Themes identified in the transcripts will be categorised using the TFA (Sekhon et al., 2017). The TFA consists of seven component constructs; affective attitude, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness and self-efficacy. How we anticipate these will fit with the study is outlined in Table 2.

The themes will be identified, compared, refined and coded using the Framework Analysis technique (Gale et al., 2013), with the component constructs of the TFA to form columns in the framework. This will consist of:

1. Verbatim transcription of data.
2. Familiarisation with the dataset – this is usually more important when different members of the research team do data collection and others transcribe (Gale et al., 2013). In this particular study the researcher will conduct the interviews and transcribe all data.
3. Coding – All transcripts will be read and coded, principally according to the TFA, with specific statements being grouped as theme form.
4. At the point at which the coding begins to stabilise, the themes will be grouped together under categories starting with the components of the TFA, and then other categories as needed to capture the meanings in all themes. Similar and different characteristics of themes

Table 1. Summary of Topics Covered in Interviews.

Current Medication – Exploring Knowledge and Burden
Previous experiences around deprescribing and problems with their medicines
Willingness to deprescribe
Ownership of medication
Views around pharmacist role

MANAGEMENT OF DISTRESS:

If participant shows emotional stress expected with the type of questions being asked, offer support and extend the opportunity to:

a. Stop the interview
b. Regroup
c. Continue

If the participant's responses seems to show high level of stress or emotional distress, indicated by crying, or shaking or shows a strong desire to discontinue the interview.

The interview should be stopped immediately.

Then the following steps will be followed:

1. Offer support and signpost participant to "What if there is a problem or something goes wrong?" section of Participant Information Sheet

2. Liaise with nurse in charge of the area at that time

3. Consider informing medical team if deemed necessary (as determined by the researcher, who is a healthcare professional)

Following the incident both the Sponsor and Chief Investigator will be informed within 24 hours.
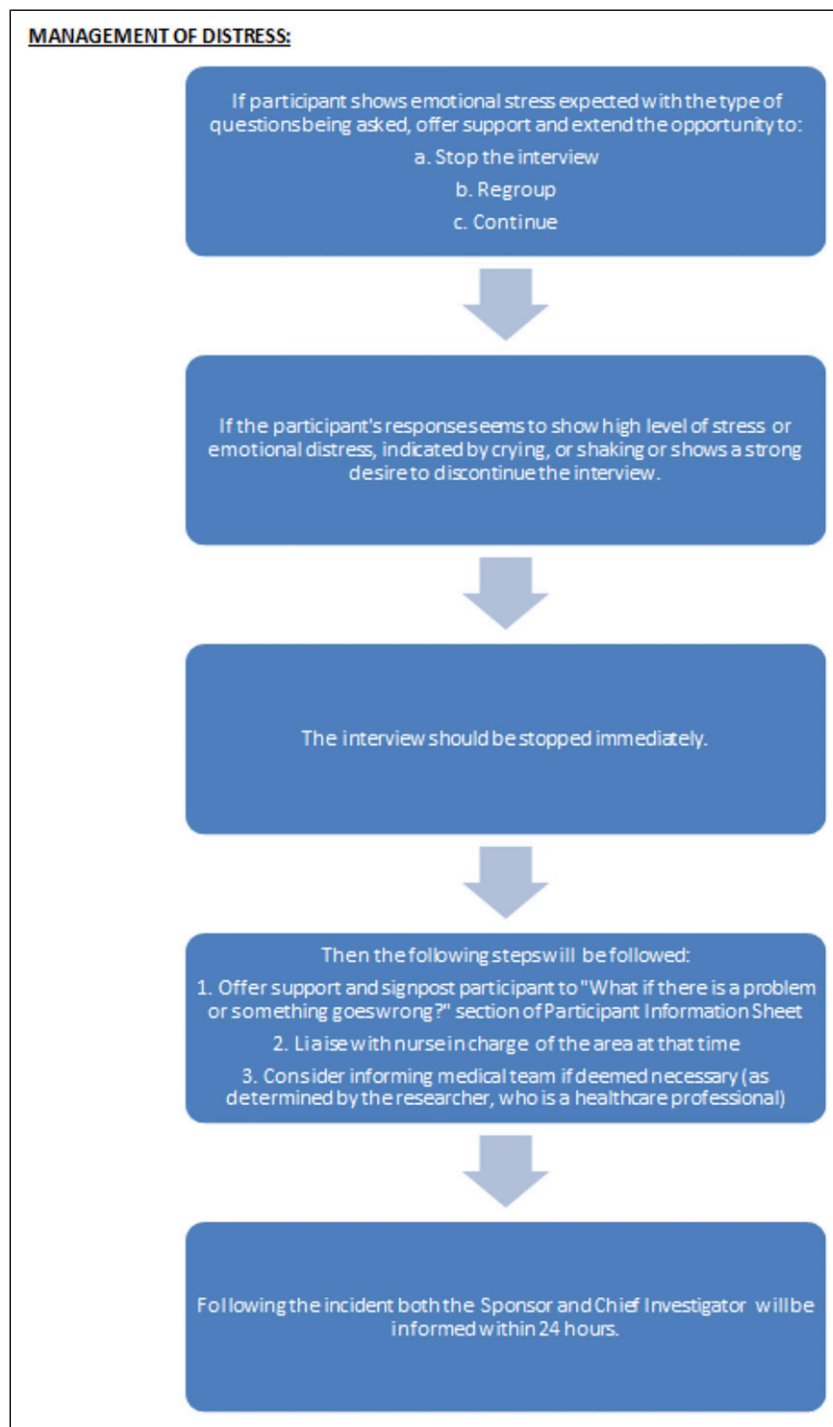
Figure 1. Distress protocol.

will be identified to avoid overlap between themes, which will either reinforce the existing concept expressed in the theme or will be defined as a new theme.

5. Applying the analytical framework – The remaining transcripts will be coded using this analytical framework.
6. Charting data into the framework matrix – Data is put onto a spreadsheet which will be generated using the categories. This will contain all themes and direct quotations to illustrate them from the transcripts.
7. Interpreting the data – Categories and themes can be further refined, where needed by comparison of the data to ensure individual views are included and a final interpretation of the data is reached (Gale et al., 2013).
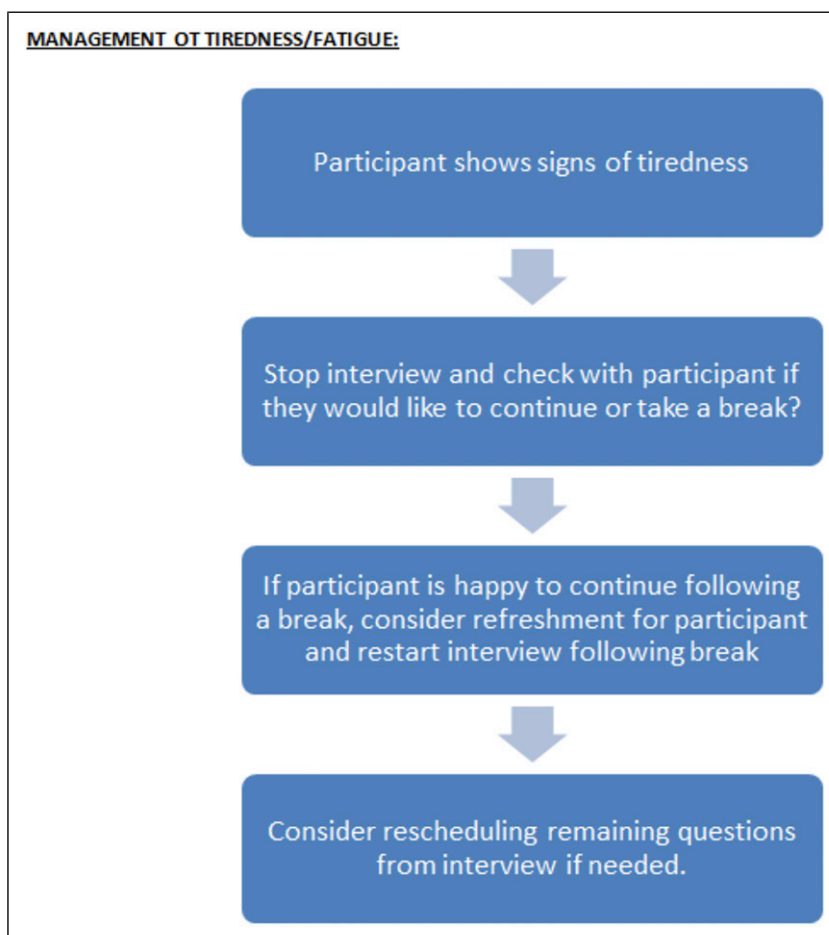
Figure 2. Fatigue protocol.

Table 2. Outline of How the TFA Will Fit With This Study.

Affective Attitude	Burden	Ethicality	Intervention Coherence	Opportunity Costs	Perceived Effectiveness	Self-Efficacy
What is their attitude towards deprescribing?	How much effort is perceived to take part in deprescribing? Is their medication a burden?	How does deprescribing fit with their values?	Does this participant understand deprescribing/ their medication?	Is there a cost? (Examples: Values/time)	Do they think deprescribing will be good for them?	Does the participant feel that they would be willing to accept a deprescribing intervention?

For this study the researcher will take a reflexive approach. This includes acknowledging that as a pharmacist, their views will likely be supportive towards the pharmacy profession and the role of the pharmacist in helping patients. In view of this being likely to affect the construction of the data, it is important that the researcher is able to see other healthcare professionals equally when interpreting the data, for example by highlighting all views about all professionals when coding. A reflexive diary will be maintained throughout the study to describe and reflect on likely influences on the data.

Discussion

This study proposes to address the lack of research exploring patients' perspectives in depth on deprescribing, particularly in the UK. Previous studies of deprescribing have tended to use questionnaires, such as the PATD and the revised PATD, which use fixed response questions, rather than allowing respondents to discuss their perspectives as they wish. The qualitative approach proposed by this study is expected to yield insights into the lived experiences of older people, especially in relation to deprescribing and consultations with health professionals about

stopping medicines. We anticipate that the findings of this study will support clinicians in undertaking deprescribing conversations with patients, at least by contributing to the debate around what constitutes best practice.

In doing this, the use of the TFA presents a novel approach to exploring deprescribing in terms of its acceptability to patients as a health intervention according to the constructs of the framework. The TFA is relatively new and there are few studies that have used it to date, but those that have done so have used it insightfully to explore the acceptability of other interventions to patients and healthcare professionals (Murphy & Gardner, 2019; Paskins et al., 2020; Pavlova et al., 2020). This gave a firm basis to choose the TFA as a theoretical framework to inform this study.

Use of an appropriate theoretical framework is a strength of this proposed study, as is the reflexive approach adopted, since these should aid the trustworthiness and the likely transferability of the findings. However, despite this, it is acknowledged that irrespective of whether the data relating to the broad topics of interest in the interviews is saturated as aimed, this will not necessarily mean the findings are widely transferrable to deprescribing in older people. This is partly because of the study being broadly limited to central England, the self-selected nature of the sample of participants, and patients' current (i.e. what they say in the interviews may not reflect what they may say on another occasion, e.g., due to how they feel about being in hospital, amongst other factors).

Nevertheless, the likely implications of the study for future research include that evaluation will be required of any change(s) in approach to deprescribing consultations that arise from the findings of this study. We would also anticipate recommending that the findings should be embedded into the prescribing-related education and training of health professionals to support patient-centred best deprescribing practice.

Author Contributions

All authors contributed to the study design. The main text was written by KC which was then revised and edited by RV and SW.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

Ethical Approval

This study has received a favourable ethical opinion from an NHS Research Ethics Committee and has Health Research Authority approval (IRAS Number – 280,134).

Informed Consent

Written informed consent will be obtained from participants to participate in this study.

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