

Knowledge, understanding and experiences of peritonitis amongst patients and their families, undertaking peritoneal dialysis: A mixed methods study protocol

Running head: Knowledge and experience of peritonitis

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Conflict of interest

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Abstract

Aim

This article is a report of a study protocol designed to examine patients' and families' knowledge and experiences of peritoneal dialysis-associated peritonitis.

Background

Peritonitis is a considerable problem for people using peritoneal dialysis, leading to antibiotics, hospitalization and decreased quality of life. For some patients, peritonitis requires changing renal replacement therapy and can be fatal. Peritonitis is distressing and some patients are unfamiliar with the signs and symptoms. Patients with better knowledge of peritonitis and adherence to peritoneal dialysis procedures have lower rates of peritonitis. Little is known about patients' and families' knowledge and experience of peritoneal dialysis-associated peritonitis in the United Kingdom.

Design

Ethical approval was gained in March 2017. To meet the study aim, a two-phase sequential explanatory mixed methods study is proposed.

Methods

Phase One: An author-developed questionnaire will be sent to patients using peritoneal dialysis at five sites in England and Wales. Patients will be asked to consider inviting a relative to participate. The questionnaire will assess peritonitis knowledge and experience. Data will be analysed statistically.

Phase Two: semi-structured interviews will be conducted with a purposive sample of Phase One participants (n=30) to explore their experiences of peritonitis in further depth. The data will be analysed thematically using Wolcott's (1994) approach.

Discussion

Data from the two phases will be synthesised to identify patients' and families' peritonitis information needs, to ensure they are appropriately supported to prevent, monitor, identify and report peritonitis.

Keywords

Mixed methods, questionnaire, interviews, peritoneal dialysis, protocol, nursing

Summary statement

Why this study is needed

- End-stage renal disease has continued to rise and the use of peritoneal dialysis is increasingly promoted. Peritonitis is a significant problem for patients using peritoneal dialysis, with adverse outcomes.
- Patients undergoing peritoneal dialysis may not be familiar with the signs and symptoms of the infection and better understanding of peritonitis is associated with lower rates of infection.
- No UK studies have examined patients' knowledge of peritoneal dialysis-associated peritonitis and few studies have considered patients' and families' experience of this complication.

Introduction

End-stage renal disease (ESRD) is the irreversible loss of kidney function, which is fatal if not treated with one of three renal replacement therapies: peritoneal dialysis (PD), haemodialysis or renal transplantation. In the UK, 58,968 individuals receive renal replacement therapies, of whom 3,638 use PD (MacNeill *et al.* 2016), while internationally of the 3,527,000 patients using therapies, 326,000 use PD (Fresenius Medical Care 2015). The number of patients requiring renal replacement therapy internationally is increasing and the increased use of PD is thus being promoted (Wankowicz 2009).

Peritoneal dialysis is a home-based treatment undertaken daily by the patient or their relative. The treatment involves the insertion of a permanent abdominal catheter through which dialysis fluid is filled into the peritoneal cavity, left to dwell and then drained out, removing uraemic toxins and excess water. Patients undertake continuous ambulatory PD (CAPD) during the day or automated PD (APD) overnight using a machine. PD enables the individual to remain at home, promotes self-management and preserves vascular access, which haemodialysis diminishes. Clinical guidelines (due for review in 2017) in the UK recommend PD as the first-line treatment for patients with residual renal function and without “significant associated comorbidities” (National Institute for Health and Clinical Excellence 2011: 9). Furthermore, cost-analyses demonstrate that PD is more cost-effective than haemodialysis (Treharne *et al.* 2014, Kerr *et al.* 2012).

However, peritonitis (infection of the peritoneum) is a significant problem in this patient population, representing the most common complication and principal cause of PD failure (Mactier 2009). PD-related infections, including peritonitis and catheter infections, are caused

by: skin or environmental contamination, catheter-related, bacteraemia, bowel and gynaecological flora (Piraino *et al.* 2011). The signs of peritonitis include pyrexia, abdominal pain and cloudy drained effluent and a diagnosis of peritonitis is made when two of the following are present:

- Cloudy PD effluent containing white blood cells >100/ml white blood cells (more than 50% neutrophils);
- Abdominal pain and tenderness and pyrexia;
- Positive gram stain or culture identifying micro-organisms in the PD effluent (Li *et al.* 2010, Main 2014, Li *et al.* 2016).

Peritonitis is treated with antibiotics, administered via oral, intravenous or intraperitoneal routes; the prescription varies according to the causative organism (Li *et al.* 2010) and severity of infection. The patient may require admission to hospital or be able to self-manage the infection at home, with support from PD nurses.

Overall, peritonitis is the cause of death for 4% of patients using PD and a contributing factor for 16% (Li *et al.* 2016). Peritonitis can cause peritoneal membrane failure (Li *et al.* 2016), which can lead to withdrawal of PD. Other complications include malnutrition, loss of ultrafiltration, fungal peritonitis, intra-abdominal sepsis requiring drainage, adhesions and rarely ileus (Levy *et al.* 2016). Peritonitis incidence varies according to PD centre (Bender *et al.* 2006, Piraino *et al.* 2011, Li *et al.* 2016) and centres are encouraged to monitor the peritonitis incidence, causative organisms and drug susceptibilities (Li *et al.* 2016). International guidelines recommend that the overall peritonitis rate in a centre should be no more than 0.5 episodes per year at risk (Li *et al.* 2016). Internationally, there is no centralised reporting of peritonitis rates, making it difficult to gain a detailed insight into the numbers of patients affected by peritonitis.

Background

Knowledge of peritonitis

Patients and their families are taught various aspects of self-management during the PD training process, many of which relate to preventing, monitoring and managing peritonitis (Bernardini *et al.* 2006). Therefore, patients and their families are required to learn multiple skills and concepts, which the PD trainer should test the person on before they are left to independently perform PD (Bernardini *et al.* 2006). Fundamental knowledge relates to patients and families understanding “what is sterile, what is clean, what is contaminated and what are the signs of infection” (Bernardini *et al.* 2006: 629). However, two qualitative studies have identified that patients and relatives may not be familiar with causes of peritonitis nor the signs and symptoms of the infection, leading to a delay in seeking help (Baillie and Lankshear 2015a, Baillie and Lankshear 2015b, Campbell *et al.* 2016). A systematic review identified that no studies have examined PD patients’ help-seeking behaviours in response to signs of infection (Griva *et al.* 2014). While participants learned from their experience (Baillie and Lankshear 2015a, Baillie and Lankshear 2015b), this is a concerning finding about whether individuals have the knowledge and skills to identify peritonitis and thus safely manage PD at home.

Five studies including the work of researchers in –Turkey (Kazancioglu *et al.* 2008a, Kazancioglu *et al.* 2008b, Ozturk *et al.* 2009), Italy (Russo *et al.* 2006) and Sudan (Sayed *et al.* 2013) have sought to quantify patients’ PD knowledge including peritonitis; one of these studies also included relatives (Russo *et al.* 2006). These studies used various author-designed questionnaires to assess knowledge, while Russo *et al.* used a questionnaire developed by Baxter Healthcare. The findings of these studies reveal a concerning picture that patients’

knowledge of peritonitis is inadequate and this correlates to their likelihood of developing peritonitis. It is evident from this research that there are gaps in patients' and relatives' knowledge related to peritonitis prevention, monitoring and identification.

Russo *et al.* (2006) identified that participants lacked knowledge in relation to signs of peritonitis, exit-site dressing and maintaining a clean dialysis environment. Participants in Sayed *et al.*'s (2013) study scored a median of 11.5/35 for knowledge about PD. Overall, 50% of participants were unable to identify signs/symptoms of peritonitis and measures to prevent peritonitis, including handwashing and exit-site care (Sayed *et al.* 2013). Kazancioglu *et al.* (2008a) identified that patients had a mean knowledge score of 79.8/100; patients scoring highest in the PD exchange procedure (17.4/20), compared with personal hygiene (14.7/20). Kazancioglu *et al.* (2008b) noted gaps in participants' knowledge, including what peritonitis is and measures to prevent it. Ozturk *et al.* (2009) identified that knowledge of personal hygiene (including hand washing) was low among study participants. Therefore, it is clear from these studies that there is scope for improvement in patients' knowledge relating to PD and infection prevention and identification.

These studies also demonstrate that patients with increased knowledge about PD and peritonitis are less likely to develop the complication. Sayed *et al.* (2013) found that patients with higher knowledge scores (in the upper quartile) had lower rates of peritonitis, exit-site infections and hospitalization, while patients who complied with the exchange procedure in Russo *et al.*'s (2006) study were less likely to develop peritonitis. Kazancioglu *et al.* (2008a) identified that the rate of peritonitis was lower in patients with higher knowledge and environment scores. Although work by these researchers was undertaken relatively recently, the studies were conducted at single sites with relatively small numbers of participants, with the exception of

Russo et al.'s (2006) study. There is also a dearth of UK studies quantifying patients' and relatives' knowledge of peritonitis. There is thus a need for further research to quantify and explore patients' and families' knowledge of peritonitis.

Impact of peritonitis

Few studies have sought to explore or quantify the impact of peritonitis on the individual, in terms of quality of life and experience of using PD. This is surprising considering the large body of literature that seeks to quantify quality of life of patients using renal replacement therapies. Interestingly, quality of life studies often exclude patients with peritonitis from their sample, which makes it challenging to understand the impact of the complication on the person's life.

Several quantitative studies have considered the impact of peritonitis on quality of life, although these studies are now dated. Research by Bakewell et al. (2002) identified that peritonitis was associated with worse quality of life in terms of patient satisfaction. Furthermore, peritonitis was the main reason why patients were hospitalised and hospital admission was independently associated with worse quality of life in terms of physical health, mental health and kidney disease issues (Bakewell *et al.* 2002). Peritonitis and catheter tunnel infections were reported to be the primary reasons that patients transferred to haemodialysis (Bakewell *et al.* 2002), highlighting the serious consequences of peritonitis for the individual. Juergensen *et al.* (1996) identified that patients who experienced more than one episode of peritonitis reported significantly worse quality of life, higher anxiety and somatic symptoms. In their later study, Juergensen *et al.* (1997) identified that patients with more self-reported symptoms of depression, anxiety and somatic symptoms and lower quality of life, were found

to have significantly higher rates of peritonitis. Troidle *et al.* (2003) identified that patients with depression were found to have significantly greater rates of gram-positive peritonitis. These findings suggest that there is a relationship between peritonitis and psychosocial outcomes.

A small number of qualitative studies have considered patients' and families' experiences of peritonitis. A recent South African mixed-method study explored the quality of life of patients using peritoneal dialysis and haemodialysis (Tannor *et al.* 2017). The qualitative phase of the study used focus groups and the findings highlighted that peritonitis was a common complication in the PD group. Fear of contracting peritonitis led some individuals to only undertake CAPD exchanges to the home environment (Tannor *et al.* 2017).

Baillie and Lankshear (2015a) described how maintaining an aseptic procedure during PD exchanges was an important aspect of a complex self-management regimen for patients and their families in the UK. Participants considered peritonitis a threat and worked to prevent and identify the complication. An episode of peritonitis led to increased workload for the patient and their relative, who learned how to manage the complication. Furthermore, peritonitis was associated with guilt, uncertainty and pain (Baillie and Lankshear 2015a). Participants demonstrated the stringent procedures to prevent infection, with relatives supporting patients in this process. Ongoing monitoring for signs of infection was an important aspect of self-management, but crucially some participants were not familiar with the signs of infection in reality and were confused about what they should monitor (Baillie and Lankshear 2015b). This is particularly concerning if patients and families are to effectively manage PD in the home setting. The diagnosis of peritonitis was found to be upsetting for patients and resulted in

antibiotics and hospital admission. Some participants expressed guilt and blame about the cause of the infection (Baillie and Lankshear 2015b).

An Australian study by Campbell *et al.* (2016) described the ongoing vigilance required to monitor for peritonitis and, similarly to Baillie and Lankshear (2015b), participants struggled to recognise the first signs and symptoms of peritonitis. Importantly, participants who identified peritonitis later experienced worse pain and hospitalization. During an episode of peritonitis participants experienced severe pain, which they compared to labour pain and were fearful they would die. The consequences of infection, such as vomiting and increased dependence, were embarrassing for patients (Campbell *et al.* 2016). Hospitalization due to peritonitis was very difficult for patients, who were then separated from their children, needed additional support from family, were unable to work and reported poor experiences in hospital. The follow-up after an episode of peritonitis, including intraperitoneal antibiotics and hospital appointments, was also seen as frustrating (Campbell *et al.* 2016).

Overall, there is only limited evidence available that has considered the impact of peritonitis on the individual and their family. The available research reveals a relationship between peritonitis, depression, anxiety and quality of life. Furthermore, many of the papers are now dated, with PD and peritonitis management changing since the publication of the earlier studies. Therefore, there is significant scope for further research to consider the impact of this common but serious complication on the lives of patients and their families. This research protocol presents a proposed study that will examine patients' and families' knowledge and experience of PD-associated peritonitis.

The Study

Aim

The aim of this mixed methods study is to examine patients' and families' knowledge and experiences of PD-associated peritonitis.

Objectives:

1. Design, pilot and use a structured questionnaire to identify patients' and families' knowledge and experience of peritonitis, including what causes the complication, how it can be prevented, signs of infection, what action should be taken on suspicion of the infection, whether they have experienced peritonitis and what happened if they did;
2. Explore in depth patients' and families' knowledge and experiences of peritonitis via semi-structured interviews, including steps to prevent and monitor for infection and symptoms, diagnosis, treatment and impact of peritonitis;
3. Synthesise the quantitative and qualitative data.

Study design

To meet the aim and objectives, this study will adopt a sequential explanatory mixed methods design (Creswell *et al.* 2003), encompassing firstly a survey of patients and their relatives to identify participants' knowledge and experience of peritonitis and secondly semi-structured interviews with a purposive sample of survey respondents. The findings from the interviews

will provide further context and enable an in-depth understanding of patient and families knowledge and experience of peritonitis (Kroll and Neri 2009).

Recruitment and sampling

Five purposively selected sites will be included in the study from England and Wales, enabling the recruitment of sufficient numbers of potential participants from different National Health Service (NHS) organizations. These sites have been selected due to their geographically diverse natures and the high number of patients using PD in two of the sites.

Prospective participants will be invited to take part in the study, based on the following criteria:

Phase One:

1. Over 18 years old;
2. Able to give informed consent;
3. Using PD (either CAPD, APD or both); or used PD within one year of study start date, but now using haemodialysis or with a renal transplant;
4. An adult (>18 years old) responsible for PD of a person meeting criteria 1 and 3;
5. Able to speak, read and write in English, or read and write in Welsh.

Phase Two:

1. A participant from Phase One;
2. Able to speak in English;
3. Able to participate in an interview.

Patients who are using peritoneal dialysis, or are using haemodialysis or have a functioning renal transplant who have previously used PD within one year of the study start date, will be invited to participate. This is to ensure that a range of perspectives is gathered, including people who may have had to change therapies due to PD-associated peritonitis.

Phase One: A research nurse in each site will identify potential participants who fit the inclusion criteria and give them a study information pack. Potential participants are asked to complete a permission to contact form and return it to the research nurse, who will give these forms to the researcher. The researcher will then telephone the participant and discuss any questions they may have. The researcher will take consent over the telephone, which will be audio recorded, prior to the delivery of the questionnaire. This process is outlined in figure one and has been used successfully in previous research undertaken over the telephone (Irvine 2010). Patient participants will be asked to identify if a relative supports them to use PD. If so, they will be invited to give their relative a copy of the relative questionnaire participant information sheet.

Response rates for surveys vary considerably between participant groups and method of administration. The previously published PD knowledge surveys included between 15 and 353 participants (Kazancioglu *et al.* 2008a, Kazancioglu *et al.* 2008b, Ozturk *et al.* 2009), but the response rates are not reported. A power calculation is not appropriate for this study as a hypothesis is not being tested. The latest UK Renal Registry report identified that 354 patients use PD at the five study sites (MacNeil *et al.* 2016), the number of patients using another renal replacement therapy who previously used PD within one year of the study start date is unknown. It is also unknown how many patients will agree to include a relative in the study.

Therefore, the potential sample size is difficult to calculate and this is recognized as a limitation of the study.

Phase Two: At the end of the questionnaire, Phase One participants will be asked whether they would be willing to take part in an interview with the researcher and, if so, to provide their name, address, age, current renal replacement therapy, type of peritoneal dialysis they use or previously used (CAPD/APD) and whether they have experienced peritonitis. A maximum variation purposive sample (Patton 2002) will be selected using this information from those who have expressed an interest to participate, allowing for variety in the sample. Patients and relatives will be included to promote insight into the experiences of a range of participants. Participants will be recruited and data collected until data saturation has been reached, whereby no new themes are being revealed (Guest *et al.* 2006). It is anticipated that up to 30 patients/relatives will be included; Baillie and Lankshear (2015b) reached data saturation with 25 participants and Campbell *et al.* (2016) with 29.

Data collection

Phase One: Questionnaire

To gain an understanding of patients' and families' knowledge, understanding and experience of peritonitis, a telephone questionnaire will be administered. This structured approach will enable the generation of comparable data (de Vaus 2002), providing insight into the perspectives of a sample of participants using peritoneal dialysis.

Due to the demands of managing PD at home, the questionnaire is structured and includes simple yes/no and "select all that apply" questions and the length is limited to reduce burden

to participants. Rattray and Jones (2005) highlight that multiple choice and dichotomous yes/no questions are a suitable approach for knowledge questionnaires. However, some questions provide space for free text comments, to ensure the questionnaire captures participants' knowledge if different from the options provided. The research team, nephrology healthcare professionals, researchers and a lay representative (transplant recipient, previous PD user) reviewed and provided feedback on the questionnaire. A statistician was consulted to ensure the questions were appropriately formatted to maximize data analysis.

The questionnaire consists of three sections: knowledge of peritonitis; experience of peritonitis; demographic questions; as outlined in Table One. Demographic questions were included at the end of the questionnaire to engage participants, as recommended by Rattray and Jones (2005). Parts one and two of the questionnaire are the same for patients and relatives. Part three of the questionnaire differs for patients and relatives, with the relative version including additional questions about the patient as well as the participant (relative). Each section is described below.

Part One: Knowledge of peritonitis

The first part of the questionnaire asks respondents 9 questions about their knowledge of peritonitis (8 questions for patients using CAPD). These questions were developed from previously used questionnaires (Kazancioglu *et al.* 2008a, Ozturk *et al.* 2009, Russo *et al.* 2006, Sayed *et al.* 2013), clinical guidelines (Li *et al.* 2016), renal textbooks (Main 2014, Levy *et al.* 2016), patient literature (Oakley 2016) and dialysis company literature (Baxter 2009). Overall, the correct answers add up to a score of 31 (30 for CAPD patients).

Part Two: Experience of peritonitis

Part two of the questionnaire encompasses up to eight questions relating to patients' experiences of peritonitis. While experience of peritonitis will primarily be investigated during the interviews with participants in phase two, where the topic can be explored in-depth, the questionnaire questions enable the generation of comparable data providing an overview. There are no previous questionnaires that have sought to examine patients'/relatives' experiences of peritonitis and the questions were thus generated through clinical guidelines (Bernardini *et al.* 2006, Figueiredo *et al.* 2016, Li *et al.* 2016), questions from part one of the questionnaire and earlier qualitative research on experience of peritonitis (Baillie and Lankshear 2015b). There is not a correct score total for this section.

Part Three: Demographic questions

The third part of the questionnaire includes demographic questions and questions about end-stage renal disease to allow understanding of the characteristics of those participants who complete the questionnaire. The patient questionnaire includes up to 12 questions and the relative version up to 18. The questions were written with reference to Office for National Statistics guides (Office for National Statistics 2015b, Office for National Statistics 2015a) and UK Renal Registry reports (MacNeill *et al.* 2016).

The questionnaire will be piloted with the first ten participants at the first study site. This will involve asking participants whether they think the questions make sense and are clear and whether any questions should be added (Sapsford 2007). If only minor changes are required, these responses will be included in the main study data collection.

Phase Two: Semi-Structured Interviews

Following on from Phase One, semi-structured interviews will be conducted. Participants will be given the option whether to take part in an interview over the telephone/skype or face-to-face; these approaches have been successfully used with this population in previous studies (Baillie and Lankshear 2015b, Campbell *et al.* 2016). For telephone or skype interviews, consent will be taken as described in Phase One. Consent for interviews in person will involve both the participant and researcher signing the consent form together in person.

Participants will be interviewed using a semi-structured approach about their knowledge, understanding and experience of peritonitis, enabling the generation of rich data (Heyl 2007). In particular, interviews will focus on experience of peritonitis, which cannot be fully explored in a structured survey. An interview schedule has been developed with reference to the literature, but will be informed by Phase One findings. For example, if an area of concern has been identified in the questionnaire data, this will be explored in the interviews, such as training following an episode of peritonitis. The interviews will be conversational (Spradley 1979), ensuring that participants talk about issues important to them.

Interviews will be digitally audio recorded and will last around 45 minutes. Audio recordings will be transcribed verbatim by a professional transcriber. Patients and relatives may be interviewed together or separately, according to their preference, but families often expect to be interviewed together (Baillie and Lankshear 2015a), due to their mutual experience of a long-term condition.

Data analysis

Phase One: Initially, a classification system will be created, enabling the data to be coded manually in an Excel spreadsheet. Data will then be analysed using SPSS 20. The results will

be reported as numbers with percentages, mean \pm standard deviation (SD) and/or median values. Appropriate parametric/nonparametric tests will be applied on a question by question basis. Correlation will be used to measure the relationship between variables. The level of significance will be set at <0.05 .

Phase Two: Data analysis will commence during data generation, ensuring an iterative approach (Hammersley and Atkinson 1995). The data will be managed using NVivo 11 and the data will be analysed thematically, adopting Wolcott's (1994) approach: Description, Analysis and Interpretation. This approach involves identifying a coding framework and coding the data, considering the meaning of the data and identifying themes and finally interpreting these themes and considering them in relation to the wider literature.

Interpretation: The data from the two phases will then be synthesized. This is a crucial stage of a mixed methods study (Kroll and Neri 2009), a requirement of which is the integration of the data from the different methods. Creswell *et al.* (2003) recommend that data from sequential explanatory mixed methods studies are integrated at the interpretation phase of the study. Therefore, the qualitative and quantitative data considering participants' knowledge of peritonitis will be interpreted together, as will the data considering participants' experience of peritonitis.

Ethical considerations

This study will be undertaken with reference to the Research Governance Frameworks for Wales (Welsh Assembly Government 2009) and England (Department of Health 2005). University Sponsorship was gained. Proportionate review from an NHS Research Ethics

Committee was approved in March 2017. Informed consent will be taken prior to data collection in both phases of the study following the stages as outlined above. The participant information sheets were written in accordance with Health Research Authority (2017) and Royal College of Nursing (2009) guidelines. All data will be anonymized and stored in line with the Data Protection Act (United Kingdom 1998). Participants in Phase Two will be assigned a pseudonym.

The researcher will establish clear referral pathways to a member of the clinical team if they have any concerns about the health or wellbeing of a participants, in line with professional responsibilities (Nursing and Midwifery Council 2015) and the Research Governance Framework (Welsh Assembly Government 2009).

Rigour

To promote integrity and quality in this mixed methods study, appropriate validation strategies will be applied for each phase of the study (Giddings and Grant 2009).

Phase One: To ensure content validity the questionnaire items were generated with input from experts in the field, including a renal patient and reviewing relevant literature (Ratray and Jones 2005). Following ethical approval, the questionnaire will be piloted as described above in one site to identify questions that lack clarity (Ratray and Jones 2005). Questions in part three of the questionnaire will enable the sample to be described and compared with UK Renal Registry data to see how representative the sample is of the PD population. This will be particularly useful to increase validity as the study sample cannot be randomly selected (Sapsford 2007).

Phase Two: To ensure the trustworthiness of the research credibility, transferability, dependability and confirmability will be considered (Guba and Lincoln 1989). Credibility will be promoted in this study by interviewing both patients and relatives (Denscombe 2010). Furthermore, throughout data collection and analysis a research journal will be completed documenting decisions and choices (Coffey and Atkinson 1996, Finlay 2003, Koch 1994), which is an important aspect of researcher reflexivity (Koch 1994). Fieldnotes will also be written following each interview to contextualize the interactions (Coffey and Atkinson 1996). To increase the transferability of the study findings, each study site will be described and information about individual participants will be documented at the start of each semi-structured interview (Guba and Lincoln 1989). The dependability and confirmability of the research will be promoted by completing an audit trail (Koch 1994).

Discussion

This protocol has outlined a proposed mixed methods study that will use a questionnaire and interviews, with patients and relatives, at five sites in England and Wales. It is anticipated that the findings of this study will be used to develop an intervention to meet the information and support needs of this population, which will then be tested in a future study. Therefore, this study fits in the “development” element of the Medical Research Council (2006) framework for developing and evaluating complex interventions.

Limitations

There are acknowledged limitations to this study. The sample in Phase One is not a random sample as is preferable for questionnaire studies (Sapsford 2007). However, this is not feasible due to the unknown numbers of potential participants. Therefore, the approach chosen will ensure that all patients and relatives meeting the inclusion criteria at the five study sites will have the opportunity to participate in the study. The five study sites are geographically diverse and located in Wales and England, to promote diversity in the sample.

The questionnaire used for this study is author-designed and not a validated measure, which is recognized as a limitation. The previously published questionnaires on PD knowledge (Kazancioglu *et al.* 2008a, Ozturk *et al.* 2009, Russo *et al.* 2006, Sayed *et al.* 2013) are also author-designed and did not focus specifically on peritonitis knowledge. Therefore, a new peritonitis knowledge questionnaire was developed following extensive literature reviewing and with input from a variety of researchers, healthcare professionals and a patient. This questionnaire will also be piloted as described above.

Finally, it would be preferable to interview all participants in phase two in person. However, this is not feasible due to the wide geographical spread of participants. Interviewing participants from different geographical locations provides insight into the perspectives of different groups of people and gives them the opportunity to participate in research. Non face-to-face interviews have been undertaken successfully with this patient population in previous research (Campbell *et al.* 2016).

Conclusion

This protocol has outlined the rationale and design of a mixed methods study to examine the knowledge and experience of PD-associated peritonitis. There are relatively few studies that have considered this topic and the proposed study will therefore provide insight into both patients' and families' peritonitis knowledge and experience. This is necessary to ensure that patients and families are able to prevent, monitor and identify peritonitis and are supported if an episode of infection occurs. With the increasing number of patients with end-stage renal disease, this is vital to promote the wellbeing and outcomes of patients using PD.

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Figure One: Questionnaire administration process

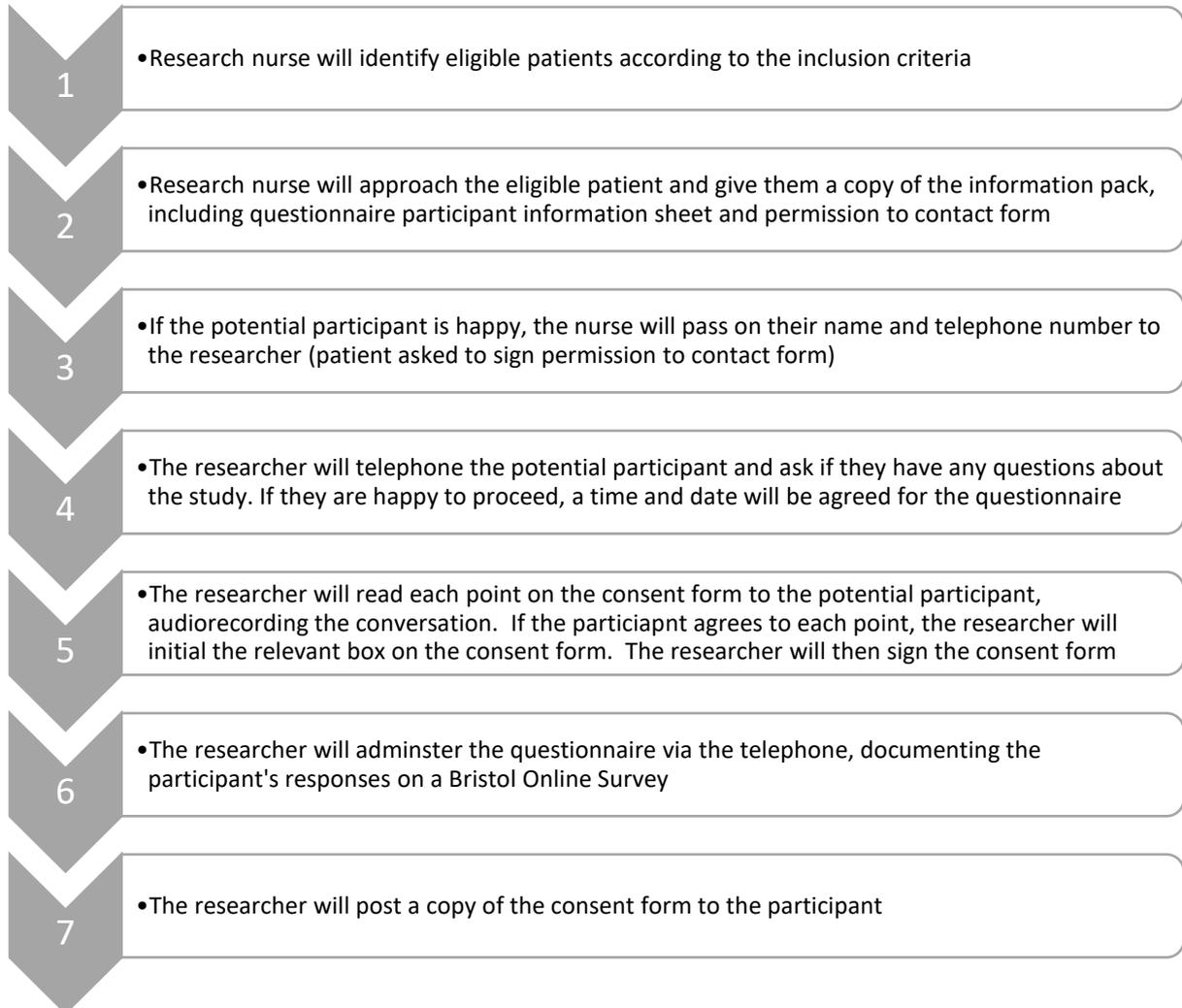


Table One: Questionnaire

Part One: Knowledge of peritonitis

1. What is peritonitis?
2. What can cause peritonitis?
3. Which of the following actions can help to reduce the risk of developing peritonitis?
4. Which of the following options are signs and symptoms of peritonitis?
5. What would you do if contamination occurred to your line during connection/ disconnection?
6. If you use APD, how often should you check the fluid you drain out?
7. What would you do if you thought you might have peritonitis?
8. What do you think the clinical team would do if they suspect you have peritonitis?
9. What are the possible serious consequences of peritonitis?

Part Two: Experience of peritonitis

1. Have you ever had peritonitis since using peritoneal dialysis?
2. What made you suspect you might have peritonitis?
3. What happened after you suspected you might have peritonitis?
4. What happened when you were told you had peritonitis?
5. Do you know what caused your peritonitis?
6. Did you receive any further training from the clinical team (nurses/doctors) to use peritoneal dialysis after you developed peritonitis?
7. How worried are you about developing peritonitis now?
8. Where do look for information about peritonitis?

Part Three: Demographic Questions

Patient questionnaire

1. Are you male or female?
2. What is your age?
3. What is you ethnic group?
4. Who do you live with?
5. Which option best describes your employment status?
6. How far do you live from your peritoneal dialysis unit?
7. What was the cause of your kidney disease?
8. Which type of kidney treatment are you currently using?

Boxes:

9. Do you currently use CAPD/APD/both/ Assisted PD?
10. How long have you used peritoneal dialysis?
11. Does anybody help you to use peritoneal dialysis?
12. Have you ever used another kidney treatment? – Box one
12. Why did you change to haemodialysis? – Box two

Relative questionnaire

1. Are you male or female?
2. What is your age?
3. What is you ethnic group?
4. Who do you live with?
5. Which option best describes your employment status?
6. Is the person you care for male or female?
7. What is their age?
8. What is their ethnic group?
9. What is your relationship to them?
10. Do you live with them?
11. Which option best describes their employment status?
12. How far do they live from their peritoneal dialysis unit?
13. What was the cause of their kidney disease?
14. Which kidney treatment are they currently using?

Boxes:

15. Does the person you care for use CAPD/APD/both/Assisted PD?

16. How long have they used peritoneal dialysis?
17. Who is responsible for carrying out their peritoneal dialysis procedure?
18. Have they ever used another kidney treatment? – Box one
18. Why did they change to haemodialysis? – Box two