Exploratory study: how does the spirituality of a group of British people with Type 2 Diabetes impact their coping and self-management of their condition?

This Proposal has been submitted as part of a Doctorate of Clinical Practice and has already been peer reviewed and passed by the Health Sciences Faculty at the University of Southampton

Author: Natasha Duke
Supervisors: Prof Andree Le May
Dr Wendy Wigley

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1 Introduction

As an advanced nurse practitioner working in general practice within a predominantly white population in Hampshire, I care for people with Type 2 Diabetes (T2D). In the clinics I run, some patients with T2D have revealed that their spiritual beliefs impact upon their self-management behaviours of diet and exercise; the extent to which they engage (or not) with treatment and their fears of disease progression. This proposal outlines a study of people with T2D. It seeks to understand if and how the spirituality of people with T2D impacts their coping and self-management of their condition. The results will be used to encourage clinicians to consider the spirituality of people with T2D when planning their care, thus giving holistic treatment.

2 Aim and Objectives of Proposed Research

It is known that poorly managed T2D leads to complications such as heart attack, kidney disease and blindness (Diabetes UK 2013; Hex et al. 2012). The current literature demonstrates that the spirituality of people with T2D does impact their coping and self-management of their condition, which will affect their risk of developing complications. However, none of the studies have been with British participants. It is not yet known if and how the spirituality of British people with T2D impacts their coping and self-management of their condition. The aim of the proposed exploratory study is to discover if and how spirituality impacts the coping and self-management of T2D of a small group of British people, and in what ways it affects these areas.

The objectives of this research will be to:

- explore if and how spirituality affects coping
- explore if and how spirituality affects the self-management behaviours of diet and exercise

The results will be used to make recommendations to clinicians caring for patients with T2D. If clinicians have evidence that the spirituality of some British patients may influence their coping and self-management, then spiritual assessment can be promoted when negotiating healthcare treatment, thus giving greater individualised care. This is in line with guidance for patients with T2D from NICE [National Institute of Health Clinical Effectiveness] (2014 p8) that recommends 'support of self-management attitudes, beliefs, knowledge and skills'.

3 Type 2 Diabetes

T2D is a metabolic disorder characterised by high blood sugar and insulin resistance. Micro-vascular, macro-vascular and neuropathic complications occur with poorly controlled T2D, such as stroke and peripheral nerve damage (Diabetes UK 2013). The self-management behaviours of maintaining a healthy diet and doing exercise are key to reducing the risk of developing these complications (NICE 2014). Research that identifies why and how people engage (or not) with self-management behaviours will help to reduce disease complications (Diabetes UK, 2005, 2013; Stride, 2008).

Obesity associated with physical inactivity in Britain is rising, and both of these are variable risk factors for T2D (Gatineau et al. 2014). Diabetes is predicted to spend 17% of the National Health Service [NHS] budget in 2035/2036, with T2D expending approximately 8 times more than other types of diabetes (Hex et al. 2012). NHS England (2014) has stated that research should identify innovative ways to reduce disease complications and improve patients' quality of life and health outcomes. Improvements in health outcomes may be made by focusing on physical, functional, social, emotional and spiritual well-being of an individual (Bredle et al. 2011; Fallowfield 2009; Peterson and Webb 2006). This research project focuses on the latter.

4 Spirituality

In the United Kingdom [UK] 2011 Census (Office for National Statistics 2011) it was noted that Christian religious affiliation was falling, although other types of spiritual beliefs were rising. Contemporary spirituality has a different construct to religion, and people may consider themselves spiritual whilst having no religious affiliation (Swinton 2010). Spirituality is now understood to be a concept relating to being human; may have nebulous boundaries, and is understood differently by different people. Spirituality appears to be the product of human experience, reflection, reasoning and culture, forms part of the nature of being, and may (or may not) involve belief or worship of a Deity/deities (Cordova 2011; Harris 2008; Hjelm et al. 2005; Polzer and Miles 2007; McSherry 2010). Religion on the other hand is defined as the belief and worship of a divine power (Oxford University Press 2014). It is understood that spirituality and religion, although being different concepts, are

intricately linked (Swinton 2010 p27). The British Humanist Association is committed to promoting non-religious beliefs of people, and welcomes the RCN definition of spirituality that includes 'respect for privacy, dignity and religious and cultural beliefs, spending time with patients giving support and reassurance especially in a time of need and showing kindness, concern and cheerfulness when giving care' (British Humanist Association 2015).

It is documented that during suffering, illness or a life changing event such as being diagnosed with T2D, spirituality comes to have a significant meaning for some individuals (Koenig 2004; Royal College of Nursing [RCN] 2011). T2D could be considered to involve illness and suffering (Rock 2010), even more so if the person has the complications of the disease (NICE 2014). The proposed research aims to find out if and how for some patients, their spirituality may impact how they cope with their T2D, and influences their approach to the self-management of their condition.

5 The Literature Review's Key Themes

A literature review was undertaken to determine what was already known about T2D and spirituality. The strengths, limitations, bias, and omissions of current research was considered, and how this sits within the national and international context (CASP UK 2013; Jesson and Lacey 2006). Thirty-seven papers linking the concepts T2D and spirituality were retrieved and read (Appendix 1). Analysis of these papers began by creating a 'Mindmap' identifying the themes (Appendix 2).

Initially, the papers were separated into concepts of spirituality and religion as shown in the Mindmap. However, twenty-four papers showed that while these two concepts

may differ they are most often inter-related. Although being religious involved spirituality, spirituality may not involve religion (Swinton 2010).

Nearly all the studies had been conducted in America. Key themes emerged, and thirteen papers were analysed in depth (Appendix 3). They revealed that:

- spirituality and religion of people with T2D affects their self-management behaviours of diet and exercise (Polzer Casarez et al. 2010; Polzer and Miles 2007).
- Complementary alternative medicine and practices (CAMP) can be linked to spirituality. In America diabetic people used CAMP more than non-diabetic people. Their CAMP use affected their self-management behaviour of diet and also medicines adherence (Amirehsani 2011; Egede et al. 2002; Jones et al. 2006).
- Ethnicity was related to spirituality. For example, African Americans were more likely to use spiritual practices than White Americans (Polzer and Miles 2007). Men from the former-Yugoslavia and Arabian cultures believed that supernatural factors and stress impact diabetes and have negative health effects (Hjelm et al. 2005).
- Gender may affect spirituality. Some studies identified that women were more likely to use spiritual practices than men (Decoster and Cummings 2005; Jones et al. 2006; Lynch et al. 2012).
- Coping styles can affect spirituality in complex ways, affecting self-management of diet and exercise (Rovner et al. 2013). This was evident in American Christians (Cordova 2011); Thai Buddhists (Thinganjana 2007); and Arabian Muslims in Sweden (Hjelm et al. 2005).

- ‘Emotion-based coping’ styles were used mostly used by women resulting in poorer T2D control, whereas ‘problem-based coping’ was used mostly by men, who had better T2D control (Decoster and Cummings 2005; Harris 2008; Hart and Grindel 2010; Lynch et al. 2012; Newlin et al. 2003; Rovner et al. 2013).

5.1 Limitations of the literature review

The transferability of American studies to a British context should be applied with caution. The healthcare provision of American people with T2D is funded differently than in Britain. In America healthcare costs are usually financed by the individual’s insurance, the employer, or the government (Rosenthal 2013; US Government 2014a, 2014b). All medicines, any services (such as a blood test or kidney scan), and every doctor’s visit will be paid for by the patient, or the organisation. Patients with T2D on low incomes in America may have no insurance, and spiritual practices and CAMP were used as an alternative, or alongside prescribed medicines (Amirehsani 2011; Bhattacharya 2012; Popoola 2005; Utz et al. 2006). By contrast, in Britain people with T2D receive the healthcare and medicines free at point of access/care. Thus the transferability of these studies to a British context is restricted.

5.2 Literature review summary

Koenig et al. (2012) have identified that in many diseases/conditions spirituality can be related positively to mental and physical health. However, the study by King et al (2013) found that those who had a spiritual view of life in the absence of a religious framework were more vulnerable to mental disorder. The review by Quinn et al.

(2001) found a belief in God may give individuals a better sense of self-control with managing T2D, or have a negative health impact if people believe that God fatalistically determines their health, and they abandon their self-management. The research by Polzer and Miles (2007) found three groups: one group saw God as helping them to perform good T2D self-management; another group believed although God did this they were submissive to his will, and any positive outcomes were attributed to God. The third group believed if they had enough faith God would heal them, and they did not perform good diabetic self-management. Polzer Casarez et al. (2010) found that for participants with T2D, some used spiritual practices to help their self-management; others used spiritual practices and self-management towards healing, but another group used spiritual practices as healing from diabetes, and did not engage in self-management. In other studies (Lundberg and Thrakul 2013; Hjelm et al. 2005) participants engaged in self-management, despite believing it their fate or divine will to have T2D. Participants' perception of T2D causality centred on the disease being hereditary, caused by stress, or the divine will (Hart and Grindel 2010; Lundberg and Thrakul 2013; Meetoo and Meetoo 2005). Whilst spirituality may give participants comfort, hope, meaning, and strength in adversity, the lack of self-management in others will lead to diabetic complications (Polzer and Miles 2007).

Much of the American literature focussed on African-Americans (Jones et al. 2006; Polzer Casarez et al. 2010; Polzer and Miles 2007; Rovner et al. 2013), because they are considered a spiritual people, with complex religious and spiritual frameworks that influence the individual, family and society (Mattis and Jagers 2001; Polzer and Miles 2007). Other studies compared White Americans with African Americans (Decoster and Cummings, 2005; Harris, 2008; Hart and Grindel, 2010).

In the British census (Office for National Statistics 2013) the only voluntary question asked 'What is your religion?', of which 7% of the population declined to answer. The Census showed 59% of the population described themselves as Christian, 25% as having no religion, and 5% as Muslim. In England and Wales, 93% of Christians are White British, with the same number for those who reported no religion. Thirty-eight percent of Muslims report their ethnicity as Pakistani. Muslims usually fast at Ramadan, and this can have significant effects on those with T2D.

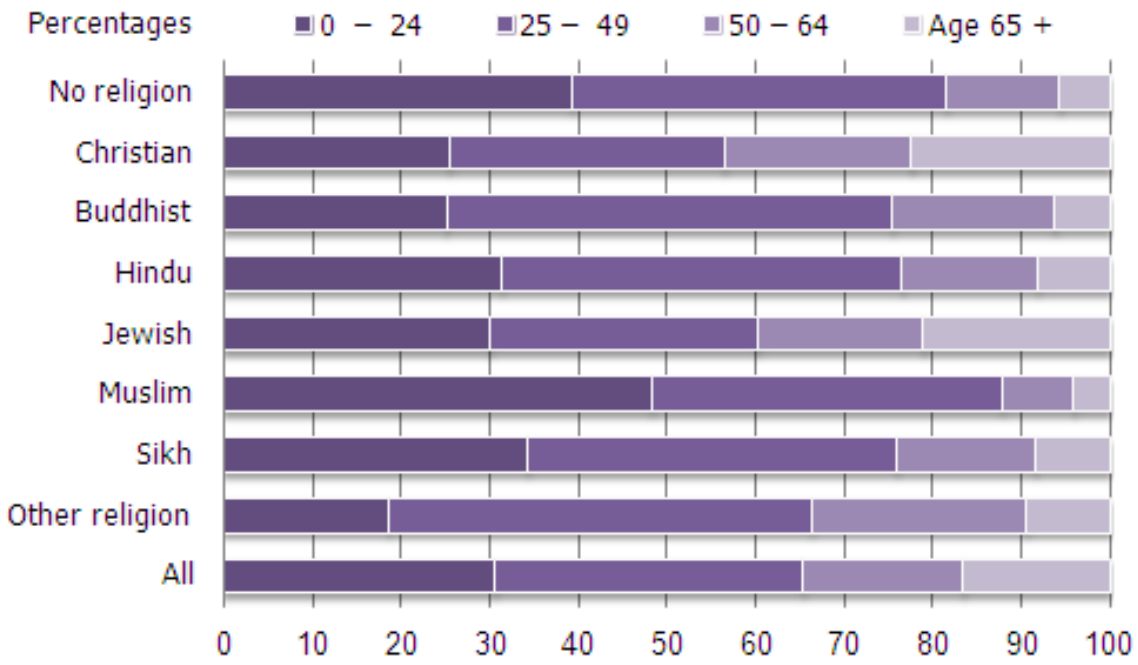


Figure 1: Religion by age in England and Wales in 2011. Office of National Statistics.

The number of people reporting no religion in Britain has increased across all age-groups, especially in the 20-24 and 40-44 year age groups. Middle age is the time when T2D is likely to occur. Although religious affiliation has fallen since the last Census in 2001, spirituality is rising (Crabtree 2012; King et al. 2013). The

spirituality of American people may be different to that of Britons, and studies need to identify how spirituality influences British population (King et al. 2013).

Although the literature review showed the spirituality of Americans affected their self-management of T2D, it is not known how the spirituality of British people influences diabetes self-management. In addition, the religiousness and spirituality of the British appears to be changing.

This literature review led to the refinement of the research question. The literature demonstrated that spirituality is unique to individuals, and can impact their coping and self-management of T2D. The key themes of spirituality, self-management, coping and ethnicity of people with T2D were considered within a British context, and the planned research question is:

'*How does the spirituality of a group of British people with T2D impact their coping and self-management of their condition?'*

Once the question had been refined, the design for the study was considered.

6 Research Design

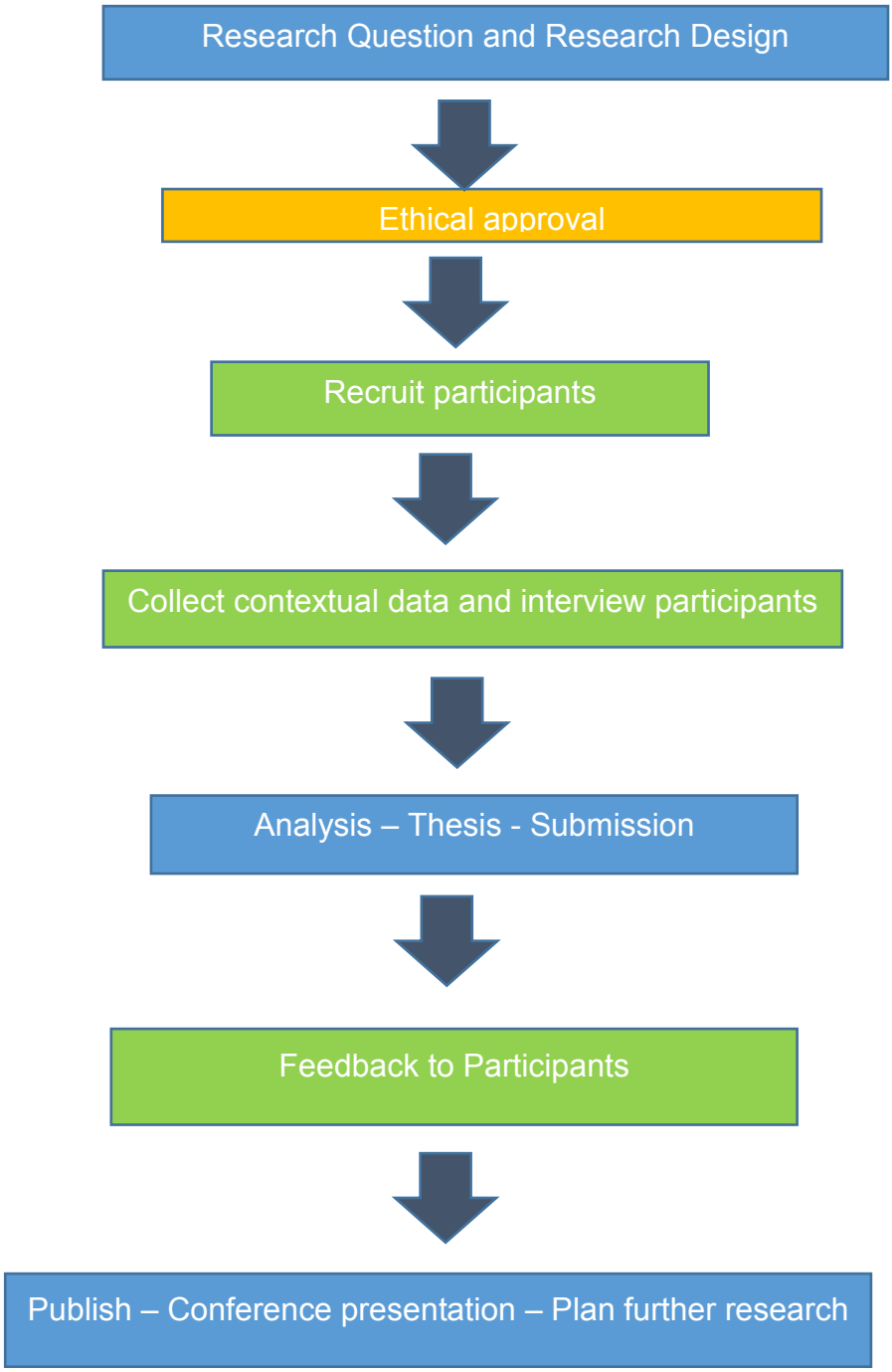
To answer the research question, a constructivist approach will be used. Following ethical approval it is planned to recruit participants for the study from diabetes clinics and GP Surgeries in Hampshire. This location has been chosen for pragmatic reasons regarding gaining permissions for recruitment of participants. I have contact with the Consultant Medical Diabetologist in the Community Diabetes Team, and also various Surgeries in Hampshire. Two Surgeries and the Consultant have already given written permission to recruit from their clinics through a Nurse, myself

or via a poster in their premises. The Community Diabetes Nurse or I will ask patients if they are interested in taking part in diabetes research, and if so, a Recruitment Pack will be given to them for their consideration. If they choose to participate, the Pack will ask them to sign the enclosed Consent Form that will be stored securely by the clinic, and the Form collected by myself. If participants respond to a Clinic poster, they will choose where to have the Recruitment pack sent (to their home or their GP Surgery where they can collect it). The Pack will request for the signed Consent Form to be returned to myself via a self-addressed envelope.

After written consent has been gained, I will contact participants to arrange recorded interviews in a location chosen by each participant. The Recruitment Pack will have advised participants that their contextual data will include their living situation (living alone or with family/partner); date of T2D diagnosis; current age; glycated haemoglobin (hba1c) blood test; body mass index and current pharmacological therapy. This data will be collected from the GP/Community Clinic to contextualize the qualitative data. These measurements will reveal how well a participant is managing their T2D. For example, a high ‘hba1c’ reveals that they do not have good control of their condition. During the interviews the coping mechanisms of the participant may reveal factors as to why their ‘hba1c’ is high. The interviews will be transcribed by myself, where I will reflexively immerse myself in all data, seeking embedded themes and patterns which I will discuss with my Supervisors.

After the thesis is written up, dissemination will be by letters to participants involved, publishing in peer-reviewed journals, teaching of colleagues, and presentations at conferences. Further research can be planned in line with the findings of this research. Figure 1 below shows the stages of the research design.

Figure 1: Overall Research Design



7 The Constructivist Paradigm

When seeking new knowledge, researchers need to establish what perspective they are using; they need to locate which paradigm to use (Bowling 2009). This research follows a constructivist approach.

This paradigm is underpinned by the principle that people develop their own understandings and meanings of the world in which they live (Guba and Lincoln 1994). These meanings may be multiple and varied, and may be related to social and historical factors – hence the term 'social constructivism' (Creswell 2007; Lincoln and Guba 2005). This paradigm seeks to understand the participants' subjective meanings to their experiences. The theories, background, values, experience and knowledge of researchers also influence what is observed and analysed. Constructionism posits that individuals 'construct their own reality' and the researcher interprets the data, so 'there are multiple interpretations', which is why it may also be referred to by some as interpretivism (Barney et al. 2007).

This paradigm is helpful when seeking to understand the lives of people that are part of a social group (e.g. a group of patients with T2D). It has the potential to reveal rich data about if and how the spirituality of participants with T2D influences the self-management of their condition. As such, it is planned to use this paradigm for this study.

8 Methods considered for this study

To understand how participants' spirituality influences their self-management, rich and descriptive data will be sought and therefore a qualitative approach is thought to be the most appropriate. Different methodologies were considered, and for participants to reveal their beliefs, reasons for actions and how they managed their T2D on a day to day basis. Phenomenology, grounded theory and the narrative method were all deliberated upon. Grounded theory was not chosen, as the aim was not to produce a theory (Strauss and Corbin 1999). The aim of the research is not to understand a phenomena as in phenomenological research (Moustakas 1994; van Manen 1990) but to have insight into how participants' spirituality impacts their coping and self-management of T2D. Therefore it is considered that a narrative approach is most appropriate method for this research.

8.1 Narratives

There is no clear agreement as to the definition of narrative and it does not fit into to one scholarly area (Reissman 1993 p17). In narrative research, Czarniawska (2004 p17) describes it as a 'spoken or written text giving an account of an event/action or series of events/actions, chronologically connected'. Creswell states 'the inquirer focuses on the stories told from the individual and arranges these stories in chronological order' (2007 p76). Labov (1997) likewise agrees with chronological sequencing, and assumes all narratives are about past events.

Narratives are unique to time, place and person and evolve as the person transitions through life, and as such a story cannot be told exactly the same twice. In most narrative research, the narrative is influenced by the questions the researcher asks,

and in a sense becomes a partner influenceing the telling of the story and the direction in which it flows. These narratives or descriptions of a series of events that impact the individual are studied to describe the experience of being human. Pinnegar and Daynes (2007) state that 'narrative' can be used to describe both the method and the phenomena of the study. In describing qualitative inquiry methods Creswell (2007 p55) states the narrative method is best for 'capturing the detailed stores of life experiences of a single life or the lives of a small number of people'. Illness narratives are useful for 'studying the world of biomedical reality, but also the illness experience and its social and cultural underpinnings' (Hyden 1997 p1) and the identity of being a person with an illness (such as T2D) (Hyden 2010). Narrative research has been used to understand what it is like living with T2D (Bhattacharya 2013; Browne et al. 2013; Snow et al. 2013).

Wengraf (2015 per comm) states narrative methods are both psychodynamic and socio-biographic in approach, and concerned with the 'inner and outer worlds' that the participant inhabits. In telling their stories participants express their conscious concerns and their unconscious cultural and societal beliefs. In my proposed research the use of narrative will help to reveal how the participant's spirituality may impact their approach to diabetic self-management and coping.

8.2 Biographic-Narrative-Interpretive Method

For this research the biographical-narrative interpretive method [BNIM] will be used. This is a method of conducting and analysing biographic narrative interviews (Chamberlayne et al. 2002; Rosenthal 2010;Wengraf 2015 per comm) and has been previously used for understanding self-management of T2D (Gomersall et al. 2012).

BNIM has also been used to understand the lives of those with other chronic illnesses, diseases or conditions (Curtin and Clarke 2005; Campbell-Green and Poland 2006; Sallinen et al. 2009; Thetford et al. 2013; Hughes 2014; Milne 2014). The study by Graham (2012) also used BNIM, in which he analysed recreational drug use and found two distinct types of emptiness: 'deficient' emptiness and a perceived 'spiritual' emptiness.

In BNIM the 'context' is important, and Wengraf (2004 p8-9, 306) refers to the context as having 'hard facts' which are part of 'objective knowledge'. In my proposed study, the 'context' would be their living situation (living alone or with a family/partner); date of diagnosis of T2D; current age; hba1c blood test; body mass index and current pharmacological therapy (bio-statistical markers). Also their address and phone number will be recorded, so that the researcher can contact them. These are part of the context of their 'lived life' (Wengraf 2004 p232), and can be verified by medical records kept by their Surgery/Clinic. Contextual data involving bio-statistical T2D markers will be collected, anonymised, and stored securely in accordance with the Data Protection Act (1998).

The 'told story' (Wengraf 2004 p232) covers the participant's narrative of what has happened to them, and may include stories about their initial diagnosis; what it is like living with T2D; how they cope with self-management of T2D, and how their spirituality may have influenced their approach to self-management of T2D. This data will anchor the lived experience of managing T2D within the historical and biological context, aiding triangulation (Denzin 1970).

The BNIM narratives will be solely concerned with listening to how the participants cope and self-manage T2D, and how their beliefs may impact this. Participants will

be offered a sequence of interviews (known as ‘sub-sessions’) that will be recorded (Wengraf 2004 Chapter 6). Participants will have been informed in their information guide prior to giving consent that interviews will be recorded, transcribed, names anonymised, and the data stored in a locked secure location in accordance with the Data Protection Act (1998) and the University of Southampton Ethics and Research Governance policy (University of Southampton 2015).

8.2.1 The BNIM Interviews

BNIM involves a series of interviews. All interviews are referred to as ‘sub-sessions’. In the first interview, there are two sub-sessions. The first sub-session is followed after a short break by a second sub-session, which will expand on topics raised in the first sub-session (Wengraf 2004 Chapter 6). The third sub-session takes place around one month later. Sub-sessions may vary dramatically in length, but each interview commonly lasts 30 – 120 minutes (Wengraf 2015 per comm). Throughout all the interviews, I will ensure that the participant is happy to proceed, not emotionally distressed, and at the end of interviews will be thanked. Potential emotional distress is discussed later in this proposal.

Wengraf (2004 p189) does not specify the ideal location for interviews, only that it should be free from interruption, distractions and comfortable. The participant will be asked to choose the location of interviews, which could be in their own home or the University. If the participant chooses the University, the relevant permissions will be sought.

8.2.2 Sub-sessions

In the first sub-session, the participant is asked a carefully constructed single question aimed at inducing a narrative (Appendix 4); this question has been formulated from consideration of the research question, and email discussion with Wengraf. No further questions, only active listening skills are utilised to enable spontaneous gestalt, whilst notes are made by the researcher. A break of around fifteen minutes allows the participant to rest, whilst notes that the researcher has made are constructed to form the questions asked in the second sub-session. These are narrative-based topic questions, and must be asked in the order that the participant raised them in the first sub-session, and use the phrases used by the participant. At the end of second sub-session, the interview finishes.

The participant will be advised that the interviewer may contact them for a second interview (the third sub-session) which is likely to be within one month. If analyses of the previous two sub-sessions raises further questions, or the research question has not been answered, the participant is contacted for a third sub-session. Here further narrative questions, as well as non-narrative questions may be asked that relate to the research question. If the participant has not yet talked about their spirituality and how or if it impacts self-management of T2D, it is in the third sub-session that this will be asked about (Appendix 4).

8.2.3 Training in interviewing

The Research Governance Framework (Department of Health [DH] 2008) recommends specific training if researchers are conducting qualitative interviews. I have attended training on qualitative interviewing through the Faculty of Health Sciences, and have completed the online 'Epigeum Ethics of Research module', and also understand the policies regarding safety of 'lone interviewing' in participants' homes (University of Southampton 2010).

I am also in contact with previous researchers who have used BNIM (Chamberlayne et al. 2002; Wengraf 2004, Milne 2014) and have a detailed guide of how to use this method (Wengraf 2015 per comm). In addition, I will attend a five day BNIM intensive training residential course in London in November 2015, which will include follow on support from Wengraf.

8.2.4 Pilot interviews

Before interviewing participants, pilot interviews will be undertaken. The BNIM training course will include, this but in addition one pilot interview will be conducted with a chosen nursing colleague, involving the three sub-sessions (Wengraf 2004 p187). I plan to ask a nursing colleague (who supports patients with T2D) to consent to giving an interview, in which they would talk about having a health problem and how their beliefs may impact their management of this condition. Although their health problem is not T2D, this pilot interview will enable me to further develop confidence in specific interviewing skills; identify potential challenges that may occur from possible conflicts due to being a nurse as well as a researcher; assist in becoming confident with recording equipment; and aid development of reflexivity skills through the use of 'memo' writing (Wengraf 2004 p209–211). Details of memo

writing is given in Section 9.2 of this proposal. Discussion and feedback will be given to the Supervision team to identify further learning that may be gleaned from this process.

9 Participation and Sample Size

Wengraf (2004 p96) states in BNIM research 'deliberate or purposeful selection' of participants is used. Sample sizes are small, and may only involve one participant, who may serve as a critical case to illustrate a specific example - such as in the case of someone with mental challenges living in a complex society (Angrosino 1994).

Factors influencing the planned sample size for this doctoral study are that BNIM inquiry is labour intensive involving 3 interviews for each participant, and each sub-session may last up to 2 hours. In exploratory qualitative studies seeking depth of analysis, it is considered 6-8 participants will yield considerable data (de Munck and Sobo 1998; Gomersall et al. 2012; Wengraf 2004), and therefore 6 participants will be recruited.

9.1 Inclusion/exclusion criteria

For participants to be included in this study, the following criteria will apply.

Table 1: Inclusion/ exclusion criteria for this study

Inclusion Criteria
Speak English
Have had T2D at least 6 months*
Have read the Participant Information Sheet, explaining this study is regarding T2D, spirituality, coping and self-management

Gives consent to access their records stored on Clinic database
Gives consent to recorded interviews
Must be over 18 years old

Exclusion Criteria
Not speak English
Have had T2D less than 6 months*
Have read the Participant Information Sheet, and decided they are not comfortable talking about their T2D, or spirituality, or coping or their self-management
Not consenting to data collection from Clinic records
Clinic records have not been kept (e.g. is a new patient to their GP)
Consent is withdrawn from the study (which could be any stage)
Under 18 years old

* Participants should not be newly diagnosed with T2D, or may still be in the phase of shock or denial (Peel et al. 2004), and not able to tell how they cope with the day to day management of their condition.

9.2 Recruitment

I will be recruiting from places where I am not known to the participants, and will present myself as a doctoral student from the University of Southampton. Although I will not hide the fact I am a nurse, it will not be disclosed unless the participant directly asks about this. If participants know I am a nurse, this could lead to them asking questions about how they should manage their T2D, which is not appropriate for this study.

Two Hampshire based GP surgeries (Alma Road Surgery and Stoneham Lane Surgery) and a Community Clinic (Southern Health NHS Foundation Trust (SHFT)) have given email permission to recruit. Participants will be recruited either:

- Via a recruitment poster at the GP surgery or Community Clinic. The poster will have details of how to contact me via email or my mobile phone, and there are 'tear off slips' with these details on each poster (Appendix 5).
- through a Diabetes Nurse asking patients if they would like to be involved in a diabetes research study, and if they are interested giving a Recruitment Pack to patients
- through me opportunistically recruiting patients at a regular diabetes educational class, run as part of the usual NHS for treatment of T2D (National Institute of Health and Clinical Excellence 2014 p8)
- SHFT have a database of diabetic patients who have already consented to be contacted as participants for research. The Consultant Diabetologist from SHFT has agreed for these patients to be contacted via email to inform them of this research. Any patients with T2D who are interested in the study would contact me via phone or email.

9.3 Recruitment Pack

A 'Recruitment Pack' will include an Information Sheet and a Consent Form (Appendix 6) given to people who may be interested in the study. The pack will either be given at one of the identified sites, or mailed to the participant if they have responded via a poster, and include a stamped envelope to return the Pack to me. The Information Sheet will invite patients to participate in research on how the self-management of T2D is impacted by peoples' beliefs. It will advise up that up to three 30-120 minute recorded interviews inviting them to talk about their experience of T2D and spirituality will be requested, at a location of their choice; and their blood tests of hba1c, current age, age of T2D diagnosis, body mass index and pharmacological therapy will be accessed from their Clinic records. It will be made clear that involvement or non-involvement in the study will not affect their T2D treatment in any way.

10 Data analysis

Mauthner and Doucet (1998 p112) have commented that 'the use of technology conveys an air of scientific objectivity onto what remains a fundamentally subjective, interpretive process'. I do not consider it necessary to use a computer software programme to aid analysis (Mauthner and Doucet 2003).

Data from the transcribed interviews will be analysed to code for patterns/themes. Thematic field analysis involves the researcher looking 'at the presentation and process of telling the story and thus can discover the structure of its construction' (Wengraf per comm 2015). This involves identifying the patterns of the 'lived life' (i.e. familial setting, the date and age at their diagnosis of T2D, their bio-statistical

markers such as blood serum hba1c, body mass index and pharmacological therapy) and the ‘told story’ and the relationship between them, and understanding how these answer the research question.

The transcript, thematic analysis and the interpretive process and interpretation will be discussed with the Supervision team to compare the researcher's analysis with that of the Supervision team.

10.1 Reflexivity and bias

Bias may occur when data are filtered through the understanding of the researcher(s) (Stern 2004). Hand (2013 p18) states that the researcher must consider their identity and position to disclose their ‘values, assumptions, prejudice, and influence’ and how this may influence the research. In this study, I will use reflexivity to consider my nursing background and personal spirituality and the extent to which this may or may not impact on the study (Anderson 2013; Mauthner and Doucet 2013).

Reflexivity entails the researcher being aware of their own effect on the processes and outcomes of research, based on the premise that it is impossible to separate the researcher from the new knowledge being generated (Anderson 2013). Given that data analysis can be seen as a method of sorting and organising data through various techniques, I will consider how to immerse myself in the data and be reflexive (Mantzoukas 2005).

I bring my experience as a nurse supporting patients with T2D, as well as experiences of listening to how patients’ spirituality has supported them or been a source of conflict for them in their self-management of T2D. My own understandings

of spirituality have been developed from growing up in Hong Kong, and the influence of Buddhism (Melton 2014). As a Christian, I have a quiet faith, and have always been interested in how spirituality may or may not influence myself and other people. I am not interested in expressing my own personal views on spirituality or T2D, and will not discuss this with patients. I am interested in hearing the voice of an individuals' experience and what it means to them.

10.2 Memos

As advised by Wengraf (2004 p210–212), I will write reflexive memos during interview, post interview and during transcribing. A reflexive journal will be kept (Jasper 2005) and engagement with the Supervisors will occur throughout this process. Immediately after each interview, I will spend 30-60 minutes writing memos in a free-associative flow writing down everything that can be remembered about the interview (e.g. feelings, processes, gestures). This ensures as much of the interview is remembered as possible. After memo writing, the recorded interview is listened to later, and memos are again written.

10.3 Transcription

Transcription is a complex part of qualitative research involving the writing down of the spoken discourse. It is acknowledged that the written account does not entirely capture the mental, social, and cultural components of the individual (Kowell and O'Connell 2013). Although the University does not offer transcription training, sources explaining how to do this will be utilised (McLellan et al. 2003; Kowell and

O'Connell 2013; University of Essex 2015). Interviews will be transcribed verbatim by myself as soon as possible after the interview, to ensure data is still freshly in mind (Wengraf 2004). It is expected each interview will take around 5-8 hours to transcribe.

11 Ethical considerations

This study will adhere to the ethical principles of autonomy, non-maleficence, and beneficence (Beauchamp and Childress 2001; University of Southampton 2012).

The participants' well-being is of paramount importance, and will be considered at all stages throughout all interviews. Participants will be reminded at each interview that they may withdraw their consent at any stage. A thank-you letter will be sent to each participant after their interview.

11.1 Consent

Participants will have received a Recruitment Pack. If participants choose to participate in the study, they will be requested to sign a Consent Form to be returned to me. If they have been recruited by a Clinic, the signed Consent Forms will be securely stored by the Clinic, and I will collect the Consent Forms weekly. If the participant has responded to a Poster and calls or emails me, a Recruitment Pack will be posted to their chosen address (i.e. home address or Clinic address) with a stamped addressed envelope to return the Consent Form to my home address.

11.2 Storage of data: maintaining confidentiality and anonymity

Patients' identity will be protected, and personal data will comply with the Data Protection Act (GOV.UK 1998) and Research Data Management Policy (University of Southampton 2015b). Data will be stored in a locked filing cabinet within my home office. My computer is password protected with antivirus software installed. Participants' names will be anonymised by the substitution of a participant number.

11.3 Participants' family or friends involvement

In my diabetes clinics, some patients attend with their partner. T2D can be an emotive condition to discuss, and patients may need support (Kadirvelu et al. 2012; The Patients Association 2015). In addition the partner may add information that is helpful, such as a difficulty the patient had encountered with their treatment, or ask additional questions that are pertinent.

In this study, I will not encourage the presence of another person, as it is possible they may interject and interrupt the narrative of the participant, potentially impacting the gestalt (Wengraf 2004 p125). If the participant wishes to include a significant person (family member or friend), I will explain how questions or comments by the other person may change the quality of the answers that the participant gives. However, it is important that the participant feels relaxed, and if the participant still wishes to have another person present, this will be consented to. Details of the person (such as verbal consent, name and relationship to the participant) will be recorded. Any interview involving another person will be discussed with the Supervisory team and Wengraf, and analysed to see if the interview is still suitable for BNIM analysis.

11.4 Risks

A Risk Assessment Form outlines possible risks to the participants and researcher, and measures that will be taken to address hazards (Appendix 7). The key hazard identified is that of emotional or spiritual distress (McSherry and Ross 2002).

11.4.1 Distress to participants/researcher

My nursing role involves consultations with patients who may become distressed when discussing emotive subjects. As when nursing, if participants become unsettled or distressed during an interview, I would listen in an empathic non-judgemental manner; ask if they are comfortable to continue with the interview, and ask if they would like to have a break or stop the interview. I would signpost them to further support arranged such as a counsellor, GP, or spiritual advisor (e.g. priest, rabbi, imam or any person they may identify). There is also potential I may become unsettled by information disclosed. If this occurs, support would be sought from the Supervisors.

11.4.2 Risky health behaviours

If the person disclosed issues that I know could seriously harm their health - such as dangerously incorrect use of insulin – they would be urged to contact their GP, or ask if they would like me to contact their GP, or the Diabetes Clinic on their behalf. In any of these instances, the Supervisors would be contacted for further advice.

12 Resources and costs

The recording equipment will be provided by the Faculty of Health Sciences, University of Southampton. Costs such as letters, stamps and other consumables will be met by myself.

13 Timetable

I aim to spend 2 days a week on this study. Work as an advanced nurse practitioner involves 3 days a week and enables me to self-fund this study. It is hoped to complete this research by October 2018.

14 Dissemination

It is an ethical obligation to ensure research findings are disseminated to the relevant bodies, such as the participants and health professionals (Yale Center for Clinical Investigation 2009). At the culmination of this study, it is anticipated that the finding will

- identify how the spirituality of people with T2D impacts their coping with their self-management
- identify if and how the spirituality of people with T2D impacts their approach to their diet
- identify if and how the spirituality of people with T2D impacts their approach to their exercise

- if spirituality impacts patients' self-management, to encourage clinicians to incorporate individual patient's spirituality into their planned care

It is planned the results of this research will be presented back to participants, presented at teaching settings/conferences and published in various peer reviewed journals. Journals will be those focused on clinical practice, T2D, and nursing. Participants will be sent a letter advising of the results of the research, and an offer will be made for me to visit them to discuss the findings if they wish this.

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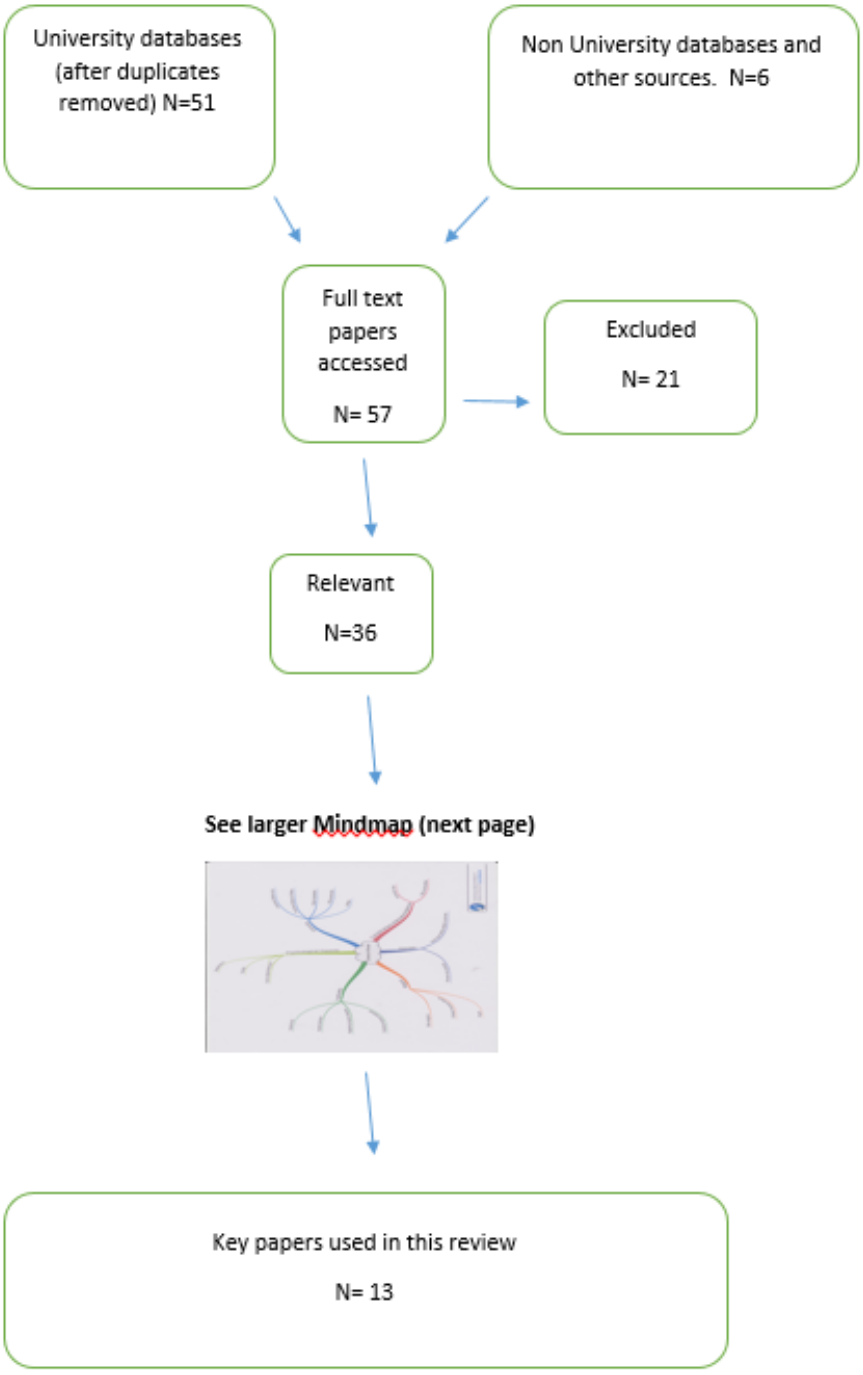
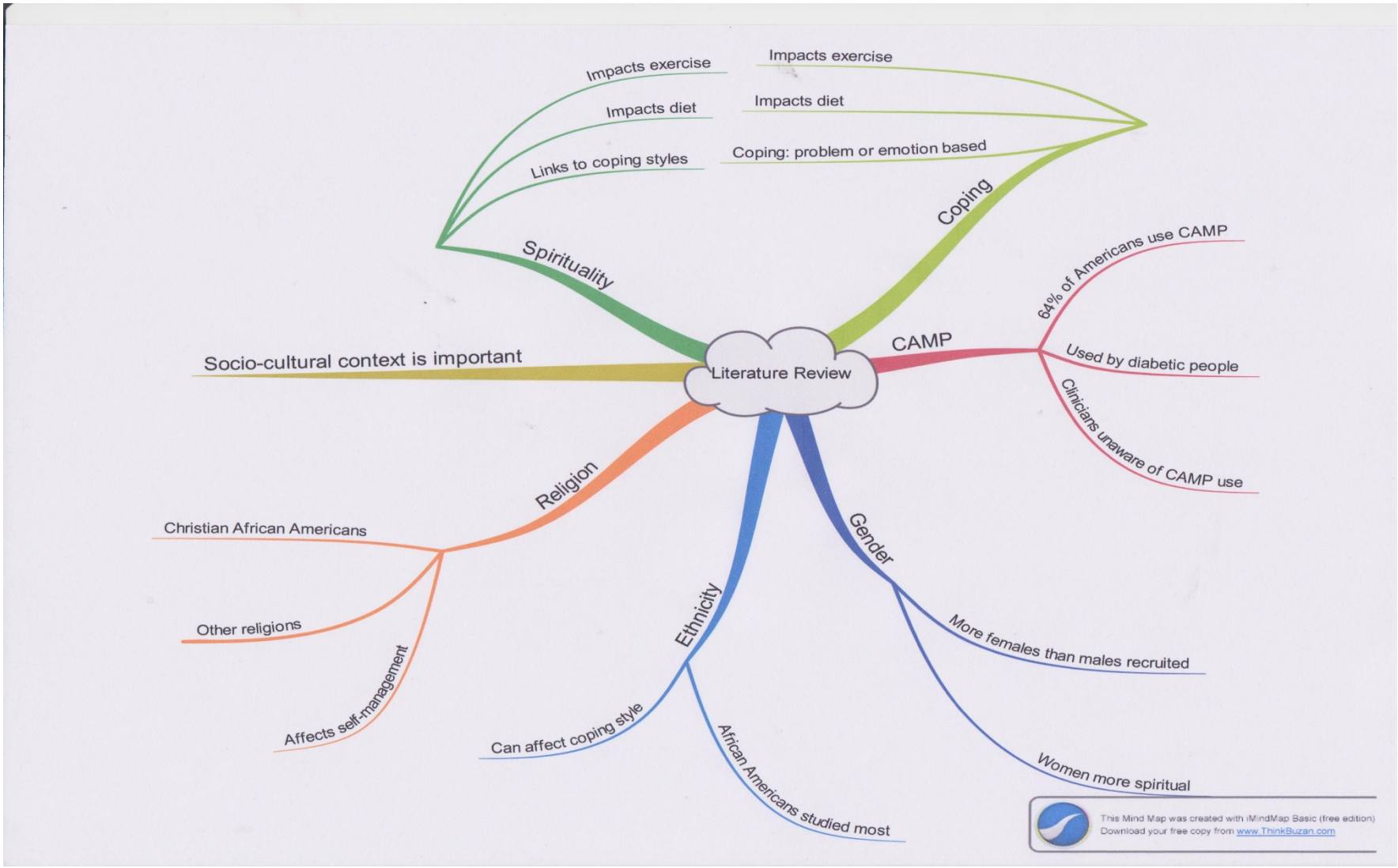
16 Appendices

Appendix 1: Adapted PRISMA



Appendix 2: Mindmap



Appendix 3: Key studies analysed

1.	Author	N	Summary	Method	Ethnicity Gender Religion	Key Findings	Limitations
	Amirehsani (2011) (PhD Thesis)	N=75	Looks at spiritual, and complementary and alternative practices (CAMP) in Latino and Hispanic people, and notes how it impacts hba1c in diabetics.	Cross sectional, correlational. Interviews. Leininger's culture care diversity and universality theory and sunrise enabler were used as the conceptual framework.	Male and female in new emerging Latino and Hispanic area in North Carolina, America. 67% female 33% male. Religion was mostly Christian.	Lower income Latino/Hispanic people are more likely to use CAMP and not inform doctor. Use CAMP because of belief in it; cheaper; difficulty with American healthcare system. Age and gender, and environmental context appear to impact cultural and social aspects; CAMP use; medical model of diabetes self-care, which all affect hba1c. 45% trusted CAMP *with* prescriptions; 44% trusted prescriptions; 5% trusted CAMP only. Some participants adjusted prescription medicines the day they used CAMP. Participants wanted doctors to include faith-based remedies as part of their care.	Specific identity of people group means findings may not be same to other non-Latino/Hispanic people. Participants may give limited answers to White researchers. Hba1c only reported as either > or < than 7%. As cross sectional, does not inform about changes over time, so cannot inform about how progressive nature of diabetes affects self-care.

2.	Author	N	Summary	Method	Ethnicity Gender Religion	Key Findings	Limitations
	Decoster and Cummings (2005)	N=34	Explored coping methods of American diabetics. Ascertained if this was influenced by gender or race, and analyzed coping with relation to diabetes.	An exploratory research design using a mixed-methodological approach, and interviews.	American Black, and American Non-Latino White. 9 Black females, 5 Black males 15 White females, 5 White males. No religion specified, although religious questions asked were related to Christianity (e.g. questions related to Bible study, or gospel music).	Diabetic adults with type 2 diabetes use different coping methods, influenced by race and gender. Participants used either problem-focused or emotion-focused methods to cope with diabetes. Problem based = better control, emotion focused = worse control. Most common coping strategies were prayer, faith in God and pre-occupy the mind.	Living in a large mid-South city in America, results may be different for other types (e.g. rural American Blacks or American Whites). Samples not even – large amounts of females.

3.	Author	N	Summary	Method	Ethnicity Gender Religion	Key Findings	Limitations
	Egede and Ellis (2010)	N=216	Describes development and validation of the Diabetes Fatalism Scale (DFS) in adults with type 2 diabetes. Three constructs: emotional distress; poor religious and spiritual coping; poor perceived self-efficacy.	35 items were derived from focus groups, literature review, and expert opinion. Pilot tested. Analysis resulted in 12-item scale. Used to test the DFS's association with diabetes self-care, hbA1c and quality of life. Multiple linear regression used to assess DFS, hbA1c comorbidity and insulin use.	American Black 61%. American White 39%. From South-East of America. Religion not identified.	Higher scores= greater diabetes fatalism. Scores not significantly correlated with age, years of education, or diabetes duration. White Americans, men, those with government or no insurance, and those with 3+ comorbid conditions had significantly higher DFS scores. DFS was significantly correlated with self-management adjusting for demographics, comorbidity and insulin use, the DFS was independently associated with increased hbA1c. The DFS is a valid and reliable measure of diabetes fatalism. Diabetes fatalism is associated with self-care problems, poor glycaemic control, and decreased quality of life.	Did not identify how recruitment occurred, so limits transferability. Participants were low income, so could be a confounding factor. Religion not identified, so limits transferability. Samples not even – large amounts of American Blacks.

4.	**Author**	**N**	**Summary**	**Method**	**Ethnicity Gender Religion**	**Key Findings**	**Limitations**
	Harris (2008) PhD Thesis	N=534	Investigates if American diabetics in Eastern North Carolina using spirituality as a coping mechanism have better health conditions.	Mailed survey. Analysed using multiple regression and multiple logistic regression.	All were American: Black 69% White 28% Other 3% 63% female 37% male Christian 72% None 4% Other 14% No data 10%	Participants using spirituality as a coping mechanism for their diabetes have significantly lower current mean hba1c. Males have significantly lower hba1c than females. American Blacks have significantly lower mean hba1c levels than other races. Higher educated have significantly lower mean hba1c levels (masters or doctoral degrees). Older participants (62 years to 105 years) have significantly lower current mean A1c levels than younger.	Relied upon self-reporting of hba1c. Data limited to 6 months, so longitudinal study would give greater validity. Samples not even – large amounts of females, and American Blacks.

5	Author	N	Summary	Method	Ethnicity Gender Religion	Key Findings	Limitations
	Hjelm et al. (2005)	N=35	Explored health and illness beliefs of middle-aged to older men from different cultural backgrounds, who were living in Sweden.	Explorative design with focus group interviews.	14 Arab males. 10 former-Yugoslavian males. 11 Swedish males.	Important health factors were being occupied/employed, income, and sexual functioning: participants believed that these affected their diabetes. Arabs and former Yugoslavians believed supernatural factors and stress have negative health effects. Some Arabs believed having diabetes may be Allah's will for them, but demonstrated better health-seeking information. Although the former-Yugoslavians described health as 'the most important thing in life', they had the least healthy lifestyle in terms of diet, exercise and smoking. Swedes focused on heredity factors, lifestyle and self-management.	Age was 39-78, so younger persons may have different outcomes. Small sample size. Used interpreters.

6	Author	N	Summary	Method	Ethnicity Gender Religion	Key Findings	Limitations
	Hart and Grindel (2010)	N=119	Examined relationship of illness representations, emotional distress, coping strategies and coping efficacy as predictors of hba1c in American diabetics from Georgia, America. Did not include spirituality.	Descriptive, cross sectional, correlational design. Used Self-Regulation Theory to analyse questionnaires.	American White 75%. American Black 21%. Other 4%. 55 male. 64 female.	Found good coping efficacy=better diabetes control. Psychosocial factors influence self-management, hba1c values and therefore diabetes outcomes. Coping efficacy accounted for 9% in variance of self-management. Illness accounted for 12% variance in self-management.	Recruited from diabetes health care programs, or health appointments, which may mean participants are more focused than non-attenders. Was cross sectional, so cannot inform about how progressive nature of diabetes affects self-care. Samples not even: large amounts of American Whites. Majority were white and well educated, which affects transferability.

7	Author	N	Summary	Method	Ethnicity Gender Religion	Key Findings	Limitations
	Jones et al. (2006)	N=68	Focus groups explored the use of CAMP, religion and spirituality with diabetic American Blacks.	Descriptive study in 2 rural communities in Central Virginia, America. This study was part of a larger study to identify facilitators and barriers to self-management of diabetes. Focus group sessions in community settings that described their use of CAMP.	American Blacks 39 female 29 men. Protestant or Baptist American Blacks.	Participants used prayer as a coping strategy; diet based therapy; and natural products. Women use CAMP more than men. These participants did not use CAMP as an alternative to prescription medicines, as in the Amirehsani (2011) study. Three groups emerged: (1) Those who use prayer and faith (2) Those who believe God helps healthcare providers (3) Those who see a link between faith and treatment.	Results may only apply to these specific groups (Protestant or Baptist Amercain Blacks).

8	Author	N	Summary	Method	Ethnicity Gender Religion	Key Findings	Limitations
	Lundberg and Thrakul (2013)	N= 48	Qualitative study to assess how religion affects diabetic self-management.	Semi-structured interviews and observation. Health Belief Model and Keonig's Theoretical Model analysed data.	Thai women in Bangkok. 19 Buddhist 29 Muslim	Religion is a way of coping: Buddhists accept fate and illness due to previous sins; Muslims believe Allah controls people's health and he can heal. Religions can help and hinder self-management. Spiritual practices helped coping. Buddhists didn't exercise whilst Muslims did exercise– but this seemed income related. Cultural factors affected diet – Buddhists eat lots of rice and found adaptation to a diabetic diet difficult. Family supported diet, exercise, medication, and doctor's visits.	Small sample size. Blood glucose data given by women was not accurate- so was not used, but raises concerns over other information given by participants. No previous data about religious practices before diagnosis.

9	Author	N	Summary	Method	Ethnicity Gender Religion	Key Findings	Limitations
	Polzer and Miles (2007)	N= 29	Aimed to develop a theoretical model about how the spirituality of American Blacks affects their diabetic self-management.	Grounded theory, using minimally structured interviews, and constant comparison.	Religious American Blacks. 60% female 40% male Included Christian Church Ministers.	Participants fell into one of three typologies: (1) Relationship and Responsibility: God is in Background (2) Relationship and Responsibility: God is in Forefront (3) Relationship and Relinquishing of Self-Management: God is Healer. These typologies varied according to how participants viewed their relationship with God, and this impacted their self-management. Spirituality was linked to the denomination of church they attended. Group 1 had mean educational level of Batchelor's degree.	Sample size only included Protestant American Blacks. Age was >42 years, so findings may not apply to younger American Black religious diabetics.

10	Author	N	Summary	Method	Ethnicity Gender Religion	Key Findings	Limitations
	Polzer Casarez et al. (2010)	N=18	Qualitative study showing American Blacks in Texas, America use spiritual orientations to help manage or cure diabetes.	Qualitative, descriptive approach with interviews.	American Blacks 4 males 14 females Christian	Black Christians found 3 cohorts: (1) use spiritual practice aiding self-management (2) spiritual practice and self-management towards healing; (3) spiritual practice as healing.	Small sample size. Samples not even – large amounts of females. Recruited only those > 40 years old, so limits transferability to younger diabetics. Recruited from Christian Churches, and senior citizens housing. Only persons interested in spirituality were likely to be recruited.

11	Author	N	Summary	Method	Ethnicity Gender Religion	Key Findings	Limitations
	Peyrot et al. (1999)	N=118	Compared type 1 and type 2 diabetics bio-psycho-social risks, comparing emotion and problem based coping.	Paper questionnaire assessing hba1c and insulin injections; stress- using Hassel's scale; coping- using Wilson scale; and socio-demo-graphic data.	Ethnicity not recorded, but recruited from Michigan hospital in America. 83% female 17% male. Religion not recorded. N= 57: Had type 1 diabetes N= 61: Had type 2 Diabetes	Relationship to stress, emotion, non-adherence to insulin are intertwined. Biological factors interact with psychosocial factors that impact hba1c. Stress and coping affect hba1c. Psychosocial factors relating to hba1c are stronger in Type 1. Relationships of psychosocial factors and glycaemic control differ for transient and chronic control: stable psychosocial resources are linked to chronic control, and stress/adherence to transient control.	Participants with Type 1 will have had disease much longer than Type 2, and this could be a confounding factor. Samples not even – large amounts of females. Type 2 were older and this could have affected coping style. Participants were drawn from hospital based clinic. By reason of actually attending hospital appointment, showed they already engaged well in treatment.

12	Author	N	Summary	Method	Ethnicity Gender Religion	Key Findings	Limitations
	Rovner et al. (2013)	N=110	Surveys analysed diabetic American Blacks, assessing present-time-orientation, and future-time-orientation with religiosity; as well as exercise; checking blood glucose and reading food labels.	Paper questionnaire survey. x^2 analysis for categorical data, and one way analysis of variance for continuous data.	American Blacks. 80% female 20% male.	Time-orientation relates to participants' focus on short or longer term consequences. Future-time-orientation participants related their current health behaviours with future disease progression. Participants engaging in exercise had significantly higher religiosity and future-time-orientation, although clear reasons for this were not identified.	Convenience sampling and older age group may influence findings. Samples not even – large amounts of females. Did not analyse type of religion, although it was implied it was Christian, as many participants attended church. Older participants' future-time orientation could be influenced by other health concerns or impending demise.

13	Author	N	Summary	Method	Ethnicity Gender Religion	Key Findings	Limitations
	Thinganjana (2007) PhD Thesis	N= 16	Describes the lived experience of spirituality of Thai immigrants in the United States who are living with type 2 diabetes.	Descriptive phenomenological method. Open ended interviews. Analysed using Colaizzi's method (1978).	Thai immigrants living in the Richmond Metropolitan Statistical Area, other cities of the State of Virginia, and New York City. 4 male 12 female. Buddhists.	Five main themes: (1) Sequela of Diabetes (2) Coming to Terms with Diabetes (3) Managing Diabetes (4) Religion is Intertwined with Spirituality (5) Cultural Patterns. Spirituality is finding meaning and purpose in life; a sense of relatedness; understanding the fundamental nature of human life; and the indispensable expression of joy, happiness, soothing, calm, peace, security, hope and inner strength. Important for clinicians to understand beliefs other than their own.	Results only applied to this specific group (Thai immigrants in America). Samples not even – large amounts of females.

Appendix 4

QUESTIONS FOR PARTICIPANTS

Version : V1
Date: 12 November 2018
Study Title: How does the spirituality of a group of British people with type 2 diabetes impact their coping and self-management of their condition?
ERGO Study ID number:
Student: Natasha Duke
Supervisors: Professor A Le May; Dr W Wigley

Interviews

Sub-sessions One and Two are on the same day, usually about 15 minutes apart.

Sub-session Three is about one month later.

Sub-session One:

The 'Single Question aimed at Inducing Narrative' for Biographic-Narrative Interview Method sub-session one interview is:

> *"As you know I'm researching people's stories of living with type 2 diabetes. Please could you tell me your story from when you first became aware that you might have diabetes up to now. You can start wherever you like. Please take all the time you need. I'll listen first, I won't interrupt. I'll just take some notes in case I have any further questions for after you've finished telling me about it all."*

Sub-session Two:

Questions may be asked only of topics that have been raised by the participant in Sub-session One; only in the order the participant raised them; only using the words

and phrases used by the participant. No other questions may be asked unless they have been raised by the participant in Sub-session One. Questions will be asked that induce narrative.

Sub-session Three:

This session allows the researcher to ask any questions related to the study, and do not have to induce narratives. Questions to be asked, if these topics have not arisen in Sub-session One and Two include:

- *What is it that gives you strength to cope with the challenges in life?*
- *Have any particular spiritual practices or religious beliefs help you cope with your diabetes?*
- *Can you tell me about how having diabetes may have impacted your diet and exercise?*

Some further questions may arise from the answers the participant gives.
The principles of BNIM will be used – any question will use the words and phrases used by the participant.

Appendix 5

Start date: Site: North Baddesley Surgery/Alma Road Surgery/Community Diabetes Clinic
End date:
Version: v1
ERGO Study ID number:

Do you have Type 2 Diabetes? Would you like to tell us what it is like living with this condition?

A lot of research focuses on the physical aspects of diabetes, but this study wants to listen to how diabetes affects people on a day to day basis, and what gives them strength and helps them cope with this condition. I am a doctoral student from the University of Southampton, and would like to hear from you if you would like to be involved in this study.

I will listen to you telling me what it is like living with diabetes, and ask you some questions to better understand how your beliefs may affect you managing your diabetes. If you are happy, I will also conduct a second interview with you about one month later.

You can decide where you would like to meet. I can come to your home, but if you prefer we can meet at the University. If you are interested, please contact Natasha Duke. You can email me at: nd2g13@soton.ac.uk, or call me on 07792 739 574. There are 'tear off slips' below with details that you can rip off to take the details home.

Contact : Natasha Duke Email: nd2g13@soton.ac.uk Call: 07792 739574	Contact : Natasha Duke Email: nd2g13@soton.ac.uk Call: 07792 739574	Contact : Natasha Duke Email: nd2g13@soton.ac.uk Call: 07792 739574	Contact : Natasha Duke Email: nd2g13@soton.ac.uk Call: 07792 739574	Contact : Natasha Duke Email: nd2g13@soton.ac.uk Call: 07792 739574	Contact : Natasha Duke Email: nd2g13@soton.ac.uk Call: 07792 739574

Appendix 6a

PARTICIPANT INFORMATION SHEET

Version: V1
Date: 12 November 2018
Study Title: How does the spirituality of a group of British people with type 2 diabetes impact their coping and self-management of their condition?
ERGO Study ID number:
Student: Natasha Duke
Supervisors: Professor A Le May; Dr W Wigley

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1. **Thank you for taking the time to read this information sheet. Please read it carefully before deciding to take part in this research. If you are happy to participate, *please sign and date the consent form enclosed in this pack.* If you have received this Recruitment Pack from your GP or Diabetes Clinic, please give the signed Consent Form to Reception. If you have received this in the post, please return the signed Consent Form in the stamped envelope to the Researcher Natasha Duke.**

2. **What is the research about?**

People with type 2 diabetes have to cope with managing their diabetes in a number of ways, e.g. managing their diet and exercise. This study would like to explore what gives people strength and helps them cope with this in day to day life. Research so far has shown that people use all sorts of ways to help them cope, and some people have found spiritual practices help them cope with having diabetes.

Spiritual practices are unique to each person. They could include prayer, meditation, complementary medicines or vitamin use, new age practices, spiritual healings,

massage, acupuncture, naturopathy, herbs, guided imagery, hypnotherapy and many others. Some people find their belief in God or gods helpful, and this gives them comfort and strength.

3. Why have I been chosen?

You have been invited to take part because you have type 2 diabetes. Anyone can take part as long as they:

- have had type 2 diabetes for at least 6 months
- are over 18 years old
- speak English
- are happy for details about their diabetes to be obtained from their GP's or Diabetes Clinic computer records (e.g. their blood test results)
- and have signed and dated a Consent Form

4. What will happen to me if I take part?

The researcher from the University of Southampton will contact you to find a time that is convenient for you to talk to her about what it is like living with type 2 diabetes. Most people would like to talk about this in their own home, but if you prefer it can take place at the University of Southampton.

The interview is recorded on a small tape recorder, and the researcher will also take some notes. There are 2 parts to the first interview, with a break of around 15 minutes in the middle. The interview can last for as long or a short as you like; the usual time is anything from around 30 minutes to 2 hours. The researcher will then arrange to have a follow up interview about one month later.

If you decided not to continue with any interview at any stage, you can simply tell the researcher, and the interview will end.

5. **Are there any benefits to me taking part?**

There are no payments given for taking part in this research. Most people take part in diabetes research because they would like to contribute to improving the lives of people with this condition.

6. **How do I know this study is safe?**

This study has already been examined internally by the Research and Governance Office at the University of Southampton, and externally examined by the NHS Research Ethics Committee, and has been deemed safe. Your usual diabetes treatment will not be affected in any way by taking part in this study.

7. **Are there are risks to me if I take part?**

Some people may feel emotional discussing their experience of living with diabetes, If you wish to stop the interview at any stage, the interviewer will finish the interview. If you wished for the researcher to delete anything from the record, she will do this.

8. **Will what I say be confidential, and who will have access to my details?**

This study complies with the University of Southampton's ethical guidelines for confidentiality. All the names of the participants involved will be anonymised by a number (e.g. P1), and details will be kept in password protected computers, or locked filing cabinets. No details in the study will refer to any person by name.

Although it is unlikely, if something you said caused the researcher to be seriously concerned that your health was in danger, she would discuss this with you and about contacting your GP.

9. What information will you be collecting about me?

In order to provide background information about your type 2 diabetes, the researcher will need to collect some information about your diabetes from your GP or Diabetes Clinic database. These will include:

- your living situation, i.e. if you are living alone or with a family/partner. It will help this study to understand if you alone manage your diabetes, or if your family/partner help you with this, for example with cooking meals.
- your date of diagnosis of type 2 diabetes
- your age
- your diabetes blood sugar test (called an 'hba1c' test)
- your body mass index
- medicines you are taking for type 2 diabetes

10. What happens if I change my mind, and don't want to be involved in the study anymore?

You can withdraw from the study at any time. You may stop an interview at any time if you don't wish to continue.

11. What happens if after I have taken part, I change my mind and don't want you keeping information about me?

If you change your mind about being involved in the study, you can withdraw your consent at any time. You would need to contact the researcher or the University of Southampton to let them know (the address is given below). In this case, all the

information about you will be deleted. This will not affect your diabetes care with your Doctor or Nurse in any way.

12. What will happen to the findings of this study?

The results of this study will be published in health professional journals, discussed at health conferences, and used in the education of health professionals. The aim of this is so that health professionals can give better, more holistic care to people with type 2 diabetes. No identifiable data will be used that will link the information directly to you.

13. Will I be told about the results of the research afterwards?

Yes. The researcher will arrange for a letter to be sent to you, to inform you of the outcomes of this research. If you choose to participate in this research, but you do not wish to know about the results of the research (when it's completed in around 2-3 years), please let the University researcher know this.

14. What are the benefits of this research?

The aim of this study is for health professionals to have a greater understanding of the complexities of living with type 2 diabetes, and to be able to offer better consultations for people living with type 2 diabetes.

15. **What happens if I have a concern, or I am unhappy with what the researcher is asking?**

If you have a concern about the study or wish to withdraw from it, you should contact Dr Wendy Wigley, who is one of the Supervisors of this study.

- You can email Dr Wigley: w.wigley@soton.ac.uk
- or write to: Dr Wigley, Faculty of Health Sciences, Room 2030, Building 45, University of Southampton, SO17 1BJ.

16. **What can I do if I want to make a complaint about this study?**

If you have more than just a concern, and you wish to make a complaint about this study, then you can:

- write to the Research Integrity and Governance Manager at the University of Southampton, Highfield SO17 1BJ
- or email the Research Integrity and Governance Manager Trudi Bartlett at rgoinfo@soton.ac.uk
- or call the Research Governance Office on 02380 595058.

Appendix 6b

Study Title: How does the spirituality of a group of people with type 2 diabetes, living in England, influence their coping and self-management of their condition? Student: Natasha Duke. Supervisors: Professor A Le May; Dr W Wigley. Version: v4. ERGO No: 18602 IRAS No: 168308 Date: 12 November 2018

Please initial each box, if you agree with the statements below.

1. I have read and understood the Participant Information Sheet (V3, 18 May 2016). ☐

2. I consent to interviews that will be recorded. I have opportunity to ask questions about the study. ☐

3. I agree to take part in this research, and agree for information about me to be used for the purpose of this and future research only. ☐

4. I understand my involvement is voluntary, and I can withdraw my consent at any time, and stop my involvement, and all information about me will be deleted. My legal rights will not be affected. ☐

5. I understand if I am unhappy with any aspect of this study I may contact the University. ☐

6. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

Data Protection

I understand that information collected about me during my participation in this study will be stored on a password protected computer and that this information will only be used for the purpose of this study. All files containing any personal data will be made anonymous.

Name of Participant…….

Signature of Participant……

Date signed by Participant…….

Name of Researcher: Natasha Duke. Signature of researcher……

Date signed by Researcher…….

<u>What to do with this form</u>: see the Participant Information Sheet, page 1, paragraph 1 about what to do if you wish to take part in the research, and have signed this form.

1 copy for participant

1 for investigator

Appendix 7

RISK ASSESSMENT OF POTENTIAL HAZARDS

Version: v1. Date: 12 November 2018

ERGO Study ID number:

Study Title: How does the spirituality of a group of British people with type 2 diabetes impact their coping and self-management of their condition?

Student: Natasha Duke

Supervisors: Professor A Le May; Dr W Wigley

Outline of study	The Participants consenting for the study will have two interviews lasting approximately 30-120 minutes with the researcher that will be recorded. The key questions asked will be as outlined in the Appendix 4: Questions for Participants
Location	Interviews: The Participant will choose whether the interview is at their home or the University. The researcher will comply with the 'Lone Working Policy' of the University of Southampton.

Hazards	The Participant may become upset or distressed. The researcher may be upset or distressed on hearing information disclosed.
Who might be exposed to identified hazards	Participants or researcher
Planned measures to manage hazards	The Participants will have already been advised that they will be asked about their experience of diabetes, and what gives them strength to cope via the Participant Information Sheet. If the Participant discloses their beliefs/spirituality/religion affects the management of their diabetes, the researcher will ask further questions about this. There is potential for the Participant to become upset when discussing aspects of their diabetes,

Planned measures to manage hazards (continued)	their beliefs, or how these influence their life. If this occurs, the researcher will offer to stop the interview; to seek external support from the GP/spiritual support, or the source that the participant identifies (e.g. priest/rabbi/imam/other person or any other source identified by the Participant). The researcher will arrange any follow up that the Participant identifies would be helpful. There is also potential the researcher could become unsettled by information disclosed. If this occurs, the researcher would seek support from the supervisors.
Risks adequately controlled?	Yes

End of Appendices