Section 4: Ethics Forms

Rachel Watterson

Doctorate in Clinical Psychology
Division of Health Research, Lancaster University
Appendix 1

Research Protocol

Title

Understanding self-conscious emotions: How partners of people living with dementia feel about themselves

Name of applicant

Rachel Watterson, Trainee Clinical Psychologist, Lancaster University.

Supervised by: Dr [redacted], Research Director, Lancaster University and

Dr [redacted], Clinical Psychologist, [redacted] Older Adults

Community Mental Health Team

Introduction

Self-conscious emotions such as pride, shame and embarrassment have received an increase in research interest over the past thirty years due to their central role in regulating and motivating an individual’s thoughts, feelings and behaviours (Tracy & Robbins, 2004). Furthermore, research has suggested that self-conscious emotions, even those which on the surface might seem associated with negative consequences, can motivate people to work hard to achieve their goals and to behave in socially appropriate ways (Leith & Baumeister, 1998). For example, individuals who experience feelings of guilt also tend to display prosocial behaviours such as empathy, altruism and caregiving (Tangney, Stuewig & Mashek, 2007). Therefore, this would suggest that self-conscious emotions have a social function which enables individuals to behave in ways which promote positive interpersonal relationships.
One proposed explanation for this is social identity theory (Tajfel, 1979) which suggests that self-conscious emotions are related to an individual’s self-identity. In particular, Borckner and Higgins (2001) proposed that individuals have different perceptions of themselves such as an ‘ideal’ self and ‘ought self’. For example, an individual’s ‘ought self’ refers to their perceived duties, obligations and responsibilities. Conversely their ‘ideal self’ reflects’ their hopes, wishes and aspirations. However, there can often be discrepancies between the two internal representations of self which can create emotional conflict for the individual. Additionally, there can be negative emotional consequences for individuals and how they perceive themselves if they perceive themselves as not meeting the standards of either their ‘ought self’ or ‘ideal self’ (Borckner & Higgins, 2001). Moreover, a positive social evaluation and consistency between an individual’s self and social identity’s can illicit positive social emotions such as pride (Tracy & Robbins, 2004). Therefore, this would suggest that self-conscious emotions derive from an individual’s perception of how congruent or different they see themselves compared to how they feel that they should or would like to be.

In addition to the growing body of research regarding the impact of self-conscious emotions, there is also a growing interest in the impact of self-conscious emotions in caregivers. For example, research with formal caregivers (healthcare workers) has begun to study the impact of self-compassion on empathy and compassionate practice towards individuals for whom they professionally care (Spandler & Stickley, 2011). However, this research base has not yet explored this in relation to informal caregivers such as family members. Therefore, it could be hypothesised that the differences in roles and expectations between formal and informal caregivers may result in differences in their own self-conscious emotions and how this impacts on their experience of their situation.

Across the world, health and social care systems are facing the challenge of caring for
an increasingly aging population (Stolz, Uden & Willman, 2004). Moreover, as many people are living longer, the number of individuals who experience chronic health conditions such as dementia is also increasing. Current rates of dementia are estimated at 47.5 million people worldwide, however this figure is set to triple by 2050 (World Health Organisation, 2015). Therefore, with dementia affecting a large proportion of people across the world there are significant social and financial implications for individuals, communities and health care systems. Specifically, increasing levels of care are being provided by family members of those with dementia as services struggle to meet the increasing need.

Consequently, in the early stages of dementia, support is often provided by family members, in particular partners. The support provided by partners may be a combination of emotional, financial and/or practical (Contador, Fernandez-Calvo, Palenzuela, Migueis & Ramos, 2012). Additionally many families choose, or in some cases have no option, to care for the individual at home as thresholds for service provision continue to rise. Moreover, individuals with dementia are encouraged to remain in their home with support for as long as possible, as research has suggested that individuals who are cared for at home have lower morbidity and mortality rates than those in institutional settings (van Houtven & Norton, 2004). However, this can have physical and mental health implications for the family member who is providing the care.

The current study was designed with a qualitative methodology in order to explicitly investigate how partners of people with dementia feel about themselves. It is suggested that qualitative methodology is utilised in the exploratory stages of research (Brown & Lloyd, 2001) and in research areas where there are significant gaps in current research knowledge (Elliott, Fischer & Rennie, 1999). Additionally, it is anticipated that a methodology such as interpretative phenomenological analysis (Smith, Flowers & Larkin, 2009) will capture the experiences of individuals who care for their partner with dementia and allow them to openly express their stories with the researcher. Semi-structured interviewing will be used to explore participants’ experiences
of self-conscious emotions in the context of their partner’s diagnosis of dementia. These subjective experiences will be subsequently analysed using IPA (Smith, et al., 2009).

**Method**

**Participants**

The study will aim to recruit a maximum of 10 participants; however a minimum of six will need to be achieved to enable the results to be thoroughly analysed. If more than 10 individuals approach the researcher to take part in the study, the first 10 individuals who can attend an interview schedule will be recruited. With regards to inclusion criterion all participants will be partners of people with a diagnosis of dementia. Furthermore, the individual with the diagnosis of dementia should be over the age of 65 years old, as the experience of individuals with a partner who has an early onset dementia may differ from those diagnosed with dementia later in life.

All participants will be under the care of a memory service, which provides specific support for individuals with memory difficulties. Moreover, in this case ‘partner’ refers to an individual who is in a relationship with someone with a dementia diagnosis with whom they have been cohabiting for at least five years prior to the diagnosis of dementia. Additionally, all participants must be over the age of eighteen and able to provide consent to participate in the study.

In terms of exclusion criteria, individuals will not be included in the study if their partner no longer lives in the same property as them. Individuals who themselves have a diagnosis of dementia will also not be included in the study due to potential differences in the dynamics of the relationship where both individuals have a diagnosis of dementia.

**Design**

As this study is interested in the experiences of individuals, it will be of qualitative design
using a semi-structured interview format. Participants will be interviewed individually by the lead researcher and transcripts will be analysed using the IPA approach described by Smith, et al. (2009).

**Procedure**

Posters will be displayed within three memory clinics from the North-West region of the UK (within the same NHS trust) asking for participation from partners whose partner has a diagnosis of dementia. In addition, research information packs will be distributed to partners of patients with a dementia diagnosis, at the end of clinic appointments by the memory nurse. Prior to the advertisement of the study, the researcher will meet with the memory nurses to give an overview of the study and also details of any inclusion and exclusion criteria.

Therefore, participants will choose to opt in to the research study and the researcher will not be aware of participant details until they contact the researcher. Potential participants can contact the researcher via email, mobile telephone or complete the expression of interest form for the researcher to contact them. This initial contact does not assume consent to participate in the study, instead it is an opportunity for participants to ask the researcher more information about the study. At no point during or following completion of the study will staff from the memory service be aware of the identities of the participants.

Participants will be interviewed individually by the lead researcher using a semi-structured interview format. Each participant will be allocated a maximum of sixty minutes to be interviewed, including time to discuss the participant information sheet, sign the consent form and answer any questions. It is anticipated that a minimum of thirty minutes will be required to adequate data to be gained from each interview, however participants can ask for the interview to be stopped at any point or the researcher may stop the interview if they feel that the participant is becoming distressed. Participants will be informed at the start of the meeting that all of the time that is spent with the researcher will be recorded using a
digital recorder, including any conversations before or after the interview.

Where possible all interviews will take place on NHS sites, primarily NHS Trust sites, where the three memory services are based. However, in order to ensure the study is more accessible for participants some interviews may be held at local GP surgeries or within their own homes.

The recordings will be transcribed by hand by the researcher. The academic supervisor of the project will also listen to an anonymised version of the first interview and comment on the transcription techniques. Once each interview has been transcribed, the recording will be deleted. The transcriptions will be saved in password protected documents on the university’s Virtual Private Network (VPN) until the project has been completed. Following the completion of the project, all electronic data will be encrypted and transferred securely to the university’s research coordinator who will save the files in password-protected file space on the university VPN. After a ten year period, all data will be destroyed.

Once transcribed, IPA will be used to analyse the data, as it will explore how participants are making sense and experience this particular situation. Key demographic information will be noted such as age, gender, length of relationship, current support networks and when their partner received a diagnosis of dementia, in order to acknowledge factors which may have an impact on how participants experience their current situation. However, in order to maintain some anonymity, participants will be invited to create an alternative name which they will be referred to throughout the study.

Proposed Analysis

The transcribed data will be analysed using IPA which aims to explore the experiences of participants and how they make sense of their current situation. The emphasis of this approach is for the researcher to become emerged in the participants’ psychological world,
which includes their beliefs, identity and own constructs of the world they live in (Smith, 2003). The verbatim accounts of participants will be transcribed and analysed using IPA (Smith et al., 2009). This particular analytic process is described as an iterative and inductive approach that involves six flexible stages.

The first stage of the analysis is to read each of the transcripts individually a number of times in order for the researcher to become familiar with the story and language of each individual participant. Each time that the text is read the researcher will write comments and thoughts in the left margin of the transcribed text, highlighting any areas of interest or potential significance. Throughout this process the researcher may notice specific language used, similarities, contradictions and repeated themes in what the participant is saying. Following the repeated reading of the entire transcript, the researcher will then start to develop initial themes in the right margin of each transcript. These themes should be developed from the original comments made in stage one, however they should be more concise and use more psychological terminology. Furthermore, it is important that the researcher continually refers back to the original comments made by the participants to ensure that the themes are capturing the meaning expressed. This process should be continued for the whole transcript and consequently any similar themes identified should be given the same theme title.

Following the identification of the emergent themes, the researcher will begin to look for connections between them. Specifically, the researcher will start to list themes in an order which has theoretical relevance or may appear more significant than others. As with previous stages it is imperative that the researcher is frequently referring back to the original transcripts to ensure that the connections are not significantly removed from the actual words of the participants. In order to support this process, the researcher may collate the direct participant quotes which relate to each theme and continually review and edit these groupings as the themes develop further. The fourth stage of this process is to produce a table of
emergent themes and to organise them in clusters of similar themes. These clusters represent superordinate themes which should be given a name representing the participants’ original quotes and initial themes. At this stage of the analysis it is important that the researcher develops a list of identifiers, in the form of page numbers and key words, for each theme indicating the exact location of the associated participant quote.

The fifth stage of this process involves the researcher moving beyond the first participant’s transcript to the analysis of the remaining transcripts. As with the first stage of the analysis, the researcher will read each of the transcripts individually a number of times in order to become familiar with the language used and potentially significant quotes. Following this the researcher will identify any emerging themes in each transcript which are similar to those identified in the first participant’s account. However, it is important that the researcher acknowledges any new themes which may occur in the later transcripts rather than attempting to fit them into the existing themes. Once themes and supporting quotes have been identified across the transcripts, a table of superordinate themes is constructed. These superordinate themes are categorised in terms of the richness and connectedness of the data contained within each theme.

The final stage of the analysis is ensuring that the write up of the findings is representative of the accounts given by the participants. This is done by using the table of themes as a basis for the write up and writing a narrative argument interspersed with verbatim accounts from participants to support the argument. Moreover, it is important in the write up to distinguish between what exactly each participant has said and the interpretations made by the researcher. Throughout this development of the narrative the researcher will start to link the superordinate themes to theories which will be expanded upon in the discussion section of the write up.
**Practical Issues: (costs/logistics)**

Potential participants will be provided with self-addressed envelopes that can be used to return to expression of interest forms to the researcher. This cost will be covered by a freepost address given by Lancaster Doctorate in Clinical Psychology (DClinPsy) programme, Lancaster University. It is proposed that all participants are interviewed within NHS Trust sites, where the three memory services are based as at least one of these locations are familiar to all participants. However, should participants struggle to attend one of these locations, local GP surgeries or participant homes may be used to conduct the interviews. In cases where interviews are conducted at GP surgeries or participant homes, the researcher will adhere to NHS Trust’s lone working policy. This will include utilising a ‘buddy’ system with another trainee at Lancaster University, with whom they will discuss the lone working procedures (page 11 of 2015 lone working policy). As per the policy, the researcher will provide the buddy with their research mobile phone number, which will be switched on throughout the interviews, in addition to a timetable and location of each interview. The lead researcher will arrange to telephone the ‘buddy’ prior to the start and at the end of each interview. As per the policy, if there is no response from the researcher following the expected end time of the interview, the ‘buddy’ will telephone the ‘nominated lead for worker safety’, which in this particular case will be the project’s field supervisor (Dr ). Furthermore, interviews will only be conducted during the working week (Monday-Friday) and during office hours (9am-5pm) to ensure that support can be sought if interviews are conducted in NHS premises.

Participants will be able to claim up to £20 expenses for travel costs from Lancaster University. The researcher will provide expenses forms to participants on the day of interview if necessary. There are no further anticipated costs to the researcher or participants.

**Ethical Concerns**
Prior to the start of the interview, issues of confidentiality will be discussed with each participant. This will involve informing them that all conversations will be confidential between the researcher, participant and academic supervisor. However, participants will be informed that should the researcher have any concerns that they or anyone else is at risk, this information will be shared with the named academic supervisor for an action plan to be formulated further. Issues of risk may involve physical, psychological, sexual or verbal abuse, as well as engaging in significant risk taking behaviour that may cause harm to the individual or other people. The researcher will always aim to discuss any breach of confidentiality with participants prior to discussing the information with a third party, so that a collaborative way of disclosing the information can be devised.

Additionally, as consent is not being sought from the individual who has a diagnosis of dementia, participants will be asked not to focus upon specific behaviours that their partner may exhibit, but instead talk about how they manage their own feelings and ways of coping. Participants will be reminded of this in the information sheet, at the start of the interview and during the interview if necessary.

It is not anticipated that the research will cause any significant distress for participants, however the researcher is aware that participating in this research may bring up some challenging issues for individual participants. However, if this was to happen during an interview, participants would be given the option for the interview to be stopped, but they will be made aware that any further conversations will continue to be recorded. This is to protect both the participant and researcher if any further action needs to be taken. There are some limits to confidentiality: if what is said in the interview concerns significant risks to the participant, or someone else. However, if the lead researcher feels that there is an immediate risk to the individual being interviewed or anyone else, local emergency services will be contacted. Additionally, should the researcher become concerned that there is a safeguarding concern
underlying the distress of the participant, then the researcher will follow safeguarding vulnerable adults policy. If possible, the researcher will inform the participant of this breach of confidentiality before it occurs. Participants will not be offered any clinical support by the researcher but will be provided with the contact details of and the Alzheimer’s Society who can provide support and advice for individuals who care for others. All participants will be reminded on these contact details at the end of each interview, in addition the details documented on the participant information sheet. Furthermore, a letter will be sent to all participant’s GPs informing them of their participation in the study. This will allow them to provide any additional support either currently or in the future.

Additionally, when participants are interviewed for the research, they will be offered the opportunity to create a pseudonym for the purpose of the study. Throughout the interviews and the final write up of the study, the researcher will refer to the participants by their pseudonym and be mindful of including any identifiable characteristics.

It is not anticipated that there will be any negative effects for the researcher following the interviews, however additional support may be sought from clinical tutors within Lancaster University if necessary.

*Timescale*

<table>
<thead>
<tr>
<th>Activity</th>
<th>Approximate timescale</th>
</tr>
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<tbody>
<tr>
<td>Ethical Application</td>
<td>February-April 2016</td>
</tr>
<tr>
<td>Recruitment of participants</td>
<td>April-June 2016</td>
</tr>
<tr>
<td>Conduct interviews</td>
<td>April-June 2016</td>
</tr>
<tr>
<td>Analyse Data</td>
<td>May-July 2016</td>
</tr>
<tr>
<td>Write up draft report</td>
<td>June-July 2016</td>
</tr>
<tr>
<td>Finalise report</td>
<td>August 2016</td>
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</table>
References


Appendix 2

NHS REC Form Reference: 16/WM/0154 IRAS Version 5.2.1

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select ‘Save’ and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Self-conscious emotions in partners of people with dementia

1. Is your project research?
- Yes
- No

2. Select one category from the list below:
- Clinical trial of an investigational medicinal product
- Clinical investigation or other study of a medical device
- Combined trial of an investigational medicinal product and an investigational medical device
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
- Basic science study involving procedures with human participants
- Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- Study involving qualitative methods only
- Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
- Study limited to working with data (specific project only)
- Research tissue bank
- Research database

If your work does not fit any of these categories, select the option below:
- Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?
- Yes
- No

b) Will you be taking new human tissue samples (or other human biological samples)?
- Yes
- No

c) Will you be using existing human tissue samples (or other human biological samples)?
- Yes
- No

3. In which countries of the UK will the research sites be located? (Tick all that apply)
3a. In which country of the UK will the lead NHS R&D office be located:

- England
- Scotland
- Wales
- Northern Ireland
- This study does not involve the NHS

4. Which review bodies are you applying to?

- HRA Approval
- NHS/HSC Research and Development offices
- Social Care Research Ethics Committee
- Research Ethics Committee
- Confidentiality Advisory Group (CAG)
- National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

5. Will any research sites in this study be NHS organisations?

- Yes
- No

5a. Are all the research costs and infrastructure costs for this study provided by an NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC) or NIHR Research Centre for Patient Safety & Service Quality in all study sites?

- Yes
- No

If yes and you have selected HRA Approval in question 4 above, your study will be processed through HRA Approval.

If yes, and you have not selected HRA Approval in question 4 above, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network (CRN) Portfolio? Please see information button for further details.

- Yes
- No

If yes, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form immediately after completing this project filter and before submitting other applications. If you have selected HRA Approval in question 4 above your study will be processed through HRA Approval. If not, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

6. Do you plan to include any participants who are children?

- Yes
- No
7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

- Yes
- No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

- Yes
- No

9. Is the study or any part of it being undertaken as an educational project?

- Yes
- No

Please describe briefly the involvement of the student(s):
The lead researcher (Rachel Blackburn) is currently enrolled on the Clinical Psychology Doctoral programme at Lancaster University. The lead researcher will be supervised by both Lancaster University staff and NHS staff.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

- Yes
- No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

- Yes
- No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

- Yes
- No
Integrated Research Application System  
Application Form for Research involving qualitative methods only

Application to NHS/HSC Research Ethics Committee

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familiar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)  
Self-conscious emotions in partners of people with dementia

Please complete these details after you have booked the REC application for review.

REC Name:  
WestMidlands-CoventryandWarwickshire

REC Reference Number:  
Submission date:  
16/WM/0154  
11/03/2016

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:  
Understanding self-conscious emotions: How partners of individuals with vascular or Alzheimer’s dementia feel about themselves

A2-1. Educational projects

Name and contact details of student(s):

Student 1

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<thead>
<tr>
<th>Title</th>
<th>Forename/Initials</th>
<th>Surname</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mrs</td>
<td>Rachel</td>
<td>Watterson</td>
</tr>
</tbody>
</table>

Address  
Clinical Psychology, Division of Health Research  
Lancaster University  
Lancaster

Post Code  
LA1 4YT

E-mail  
r.watterson@lancaster.ac.uk

Telephone  
01524 592970

Fax
Give details of the educational course or degree for which this research is being undertaken:
Name and level of course/ degree:
Clinical Psychology Doctorate

Name of educational establishment:
Lancaster University

Name and contact details of academic supervisor(s):

**Academic supervisor 1**

<table>
<thead>
<tr>
<th>Title</th>
<th>Forename/Initials</th>
<th>Surname</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr</td>
<td>Jane</td>
<td>Simpson</td>
</tr>
</tbody>
</table>

Address:
Clinical Psychology, Division of Health Research
Lancaster University
Lancaster

Post Code: LA1 4YT
E-mail: [redacted]
Telephone: 01524 592970
Fax: [redacted]

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

<table>
<thead>
<tr>
<th>Student(s)</th>
<th>Academic supervisor(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Student 1</td>
<td>Mrs Rachel Watterson</td>
</tr>
</tbody>
</table>

☐ Dr [redacted]

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- Student
- Academic supervisor
- Other

A3-1. Chief Investigator:

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<th>Title</th>
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<tbody>
<tr>
<td>Mrs</td>
<td>Rachel</td>
<td>Watterson</td>
</tr>
</tbody>
</table>

Post: Trainee Clinical Psychologist
Qualifications: BSc Applied Psychology
Employer: Lancashire Care NHS Trust
Work Address: Clinical Psychology, Division of Health Research
Lancaster University
Lancaster
Post Code: LA1 4YT
4-20

Work E-mail r.watterson@lancaster.ac.uk
* Personal E-mail
Work Telephone 01524 592970
* Personal Telephone/Mobile
Fax

* This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.

A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project? This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

<table>
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<tr>
<th>Title</th>
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</thead>
<tbody>
<tr>
<td>Ms</td>
<td></td>
<td></td>
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Address
Research Support Office, B58 Bowland Main
Lancaster University
Lancaster
Post Code LA1 4YT
E-mail ethics@lancaster.ac.uk
Telephone 01524592605
Fax

A5-1. Research reference numbers. Please give any relevant references for your study:

Applicant's/organisation's own reference number, e.g. R & D (if available):
Sponsor's/protocol number:
Protocol Version:
Protocol Date:
Funder's reference number:
Project website:

Additional reference number(s):

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<tr>
<th>Ref.Number Description</th>
<th>Reference Number</th>
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Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the “Additional reference number(s)” section.

A5-2. Is this application linked to a previous study or another current application?

☐ Yes  ☐ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of
A6-1. Summary of the study. Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments’ Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.

The current study aims to explore how self-conscious emotions impact on outcomes in partners of people diagnosed with Alzheimer's, vascular or mixed dementia. The study will use a qualitative approach to collecting data through the use of semi-structured interviews. Additionally, it is anticipated that a methodology such as interpretative phenomenological analysis (Smith, Flowers & Larkin, 2009) will capture the experiences of individuals who provide care for their partner with dementia and allow them to openly express their stories with the researcher. It is anticipated that the themes identified across the data will provide a starting point to understanding how individuals caring for their partner with dementia experience self-conscious emotions and how services may provide emotional support to these individuals.

A6-2. Summary of main issues. Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, R&D office or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

Prior to the start of the interview, issues of confidentiality will be discussed with each participant. This will involve informing them that all conversations will be confidential between the researcher, participant and academic supervisor. However, participants will be informed that should the researcher have any immediate concerns that they or anyone else is at risk, this information will be shared with the emergency services. Issues of risk may involve physical, psychological, sexual or verbal abuse, as well as engaging in significant risk taking behaviour that may cause harm to the individual or other people. The researcher will always aim to discuss any breach of confidentiality with participants prior to discussing the information with a third party, so that a collaborative way of disclosing the information can be devised.

Additionally, as consent is not being sought from the individual who has a diagnosis of dementia, participants will be asked not to focus upon specific behaviours that their spouse may exhibit, but instead talk about how they manage their own feelings and experiences. Participants will be reminded of this in the information sheet, at the start of the interview and during the interview if necessary.

It is not anticipated that the research will cause any significant distress for participants, the researcher is aware that participating in this research may bring up some challenging issues for individual participants. However, if this was to happen during an interview, participants would be given the option for the interview to be stopped, but they will be made aware that any further conversations will continue to be recorded. Participants will not be offered any clinical support by the researcher but will be provided with the contact details of Carers Centre and the Alzheimer’s Society who can provide support and advice for individuals who care for others. Participants will also be advised to seek support from their GP.

A6-3. Proportionate review of REC application The initial project filter has identified that your study may be suitable for proportionate review by a REC sub-committee. Please consult the current guidance notes from NRES and indicate whether you wish to apply through the proportionate review service or, taking into account your answer to A6-2, you consider there are ethical issues that require consideration at a full REC meeting.

- Yes - proportionate review
- No - review by full REC meeting

Further comments (optional):

Note: This question only applies to the REC application.

3. PURPOSE AND DESIGN OF THE RESEARCH
A7. Select the appropriate methodology description for this research. Please tick all that apply:

- [ ] Case series/ case note review
- [ ] Case control
- [ ] Cohort observation
- [ ] Controlled trial without randomisation
- [ ] Cross-sectional study
- [ ] Database analysis
- [ ] Epidemiology
- [ ] Feasibility/ pilot study
- [ ] Laboratory study
- [ ] Meta-analysis
- [ ] Qualitative research
- [ ] Questionnaire, interview or observation study
- [ ] Randomised controlled trial
- [ ] Other (please specify)

A10. What is the principal research question/objective? Please put this in language comprehensible to a lay person.

This study aims to explore how partners of individuals diagnosed with Alzheimer's disease, vascular dementia or mixed dementia understand self-conscious emotions.

A11. What are the secondary research questions/objectives if applicable? Please put this in language comprehensible to a lay person.

N/A

A12. What is the scientific justification for the research? Please put this in language comprehensible to a lay person.

It is anticipated that this information will develop our current understanding of the emotional experiences of partners, which may impact upon their psychological and physical wellbeing. Furthermore, these findings aim to inform the type of support systems which should be in place around the individual with dementia and their partner. The findings may also inform the pathway for future research in this area.

A13. Please summarise your design and methodology. It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.

Posters will be displayed within three memory clinics from the North-West region of the UK (within the same NHS trust) asking for participation from partners whose partner has a diagnosis of dementia. In addition, research information packs will be distributed to partners of patients with a dementia diagnosis, at the end of clinic appointments by the memory nurse. Prior to the advertisement of the study, the researcher will meet with the memory nurses to give an overview of the study and also details of any inclusion and exclusion criteria. Therefore, participants will choose to opt in to the research study and the researcher will not be aware of participant details until they contact the researcher. Potential participants can contact the researcher via email, mobile telephone or complete the expression of interest form for the researcher to contact them. This initial contact does not assume consent to participate in the study, instead it is an opportunity for participants to ask the researcher more information about the study. At no point during or following completion of the study will staff from the memory service be aware of the identities of the participants.

Participants will be interviewed individually by the lead researcher using a semi-structured interview format. Each participant will be allocated a maximum of sixty minutes to be interviewed, including time to discuss the participant information sheet, sign the consent form and answer any questions. It is anticipated that a minimum of thirty minutes will be required to adequate data to be gained from each interview, however participants can ask for the interview to be
stopped at any point or the researcher may stop the interview if they feel that the participant is becoming distressed. Participants will be informed at the start of the meeting that all of the time that is spent with the researcher will be recorded using a digital recorder, including any conversations before or after the interview.

Where possible all interviews will take place on NHS sites, primarily NHS Trust sites, where the three memory services are based. However, in order to ensure the study is more accessible for participants some interviews may be held at local GP surgeries or within their own homes. The recordings will be transcribed by hand by the researcher. The academic supervisor of the project will also listen to an anonymised version of the first interview and comment on the transcription techniques. Once each interview has been transcribed, the recording will be deleted. The transcriptions will be saved in password protected documents on the university’s Virtual Private Network (VPN) until the project has been completed. Following the completion of the project, all electronic data will be encrypted and transferred securely to the university’s research coordinator who will save the files in password-protected file space on the university VPN. After a ten year period, all data will be destroyed.

Once transcribed, IPA will be used to analyse the data, as it will explore how participants are making sense and experience this particular situation. Key demographic information will be noted such as age, gender, length of relationship, current support networks and when their partner received a diagnosis of dementia, in order to acknowledge factors which may have an impact on how participants experience their current situation. However, in order to maintain some anonymity, participants will be invited to create an alternative name which they will be referred to throughout the study.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- Design of the research
- Management of the research
- Undertaking the research
- Analysis of results
- Dissemination of findings
- None of the above

Give details of involvement, or if none please justify the absence of involvement.

One member of Lancaster University Public Involvement Network (LUPIN) has been involved in the design of materials for this study. Additionally, it is anticipated that one member of the service user group (LUPIN) will engage in a mock interview with the lead researcher as a trial of the interview schedule.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

All participants will be partners of people with a diagnosis of dementia and under the care of a memory service. Specifically, in this case partner refers to individuals who are legally married or who have been cohabiting prior to the diagnosis of dementia. Additionally, all participants must be over the age of eighteen and able to provide consent to participate in the study.

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

In terms of exclusion criteria, individuals will not be included in the study if their partner no longer lives in the same property as them. Individuals who themselves have a diagnosis of dementia will also not be included in the study due to potential differences in the dynamics of the relationship where both individuals have a diagnosis of dementia. Moreover, partners of individuals who have a diagnosis of dementias other than Alzheimer’s, vascular or mixed Alzheimer’s-vascular dementia will not be eligible to participate in this study.
A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. These include seeking consent, interviews, non-clinical observations and use of questionnaires.

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

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<thead>
<tr>
<th>Intervention or procedure</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
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<tbody>
<tr>
<td>Seeking consent</td>
<td>1</td>
<td>0</td>
<td>5 minutes</td>
<td>The lead researcher will seek consent from each participant.</td>
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<tr>
<td>1:1 interviews</td>
<td>1</td>
<td>0</td>
<td>60 minutes</td>
<td>The lead researcher will conduct all of the interviews.</td>
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A21. How long do you expect each participant to be in the study in total?

Once the participant has conducted the lead researcher to express their interest in the study, it is anticipated that participants will be interviewed within 28 days maximum. It is anticipated that a minimum of thirty minutes will be required to adequate data to be gained from each interview, however participants can ask for the interview to be stopped at any point or the researcher may stop the interview if they feel that the participant is becoming distressed. Following this, the participants will have no further contact with the study unless they wish to withdraw their data.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

It is not anticipated that the research will cause any significant distress for participants, however the researcher is aware that participating in this research may bring up some challenging issues for individual participants. However, if this was to happen during an interview, participants would be given the option for the interview to be stopped, but they will be made aware that any further conversations will continue to be recorded. This is to protect both the participant and researcher if any further action needs to be taken. Prior to the interviews starting, a clinical psychologist within the service will be identified, who can be contacted if the researcher has any immediate concerns about risks to participants or anyone else. Where possible this should be the field supervisor of the project, as they will have more in depth knowledge about the study. Participants will not be offered any clinical support by the researcher but will be provided with the contact details of Sefton Carers Centre and the Alzheimer's Society who can provide support and advice for individuals who care for others. Participants will also be advised to seek support from their GP.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

☐ Yes ☐ No

A24. What is the potential for benefit to research participants?

While there are no specific benefits for participants taking part in this research, there may be secondary benefits to participating in research generally. For example participants will be contributing to a field of research which aims to improve the quality of life for individuals in similar situations to themselves. Additionally, participants may find it helpful to discuss issues with an impartial other i.e. the lead researcher, which they may find difficult with family members or friends.

A26. What are the potential risks for the researchers themselves? (if any)
It is not anticipated that there will be any negative effects for the researcher following the interviews, however additional support may be sought from clinical tutors within Lancaster University if necessary. Lancaster's lone working policy will also apply. This includes utilising a ‘buddy’ system with another trainee at Lancaster University who will have a timetable of the scheduled interviews and location of each interview. The lead researcher will arrange to telephone the ‘buddy’ prior to the start and at the end of each interview. Furthermore, interviews will only be conducted during the working week (Monday-Friday) and during office hours (9am-5pm) to ensure that support can be sought if interviews are conducted in NHS premises.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used? For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).

In order to recruit participants posters will be displayed within three memory clinics from the North-West region (within the same NHS trust) asking for participation from spouses whose partner has a diagnosis of Alzheimer's disease, vascular or mixed dementia. In addition, research information packs will be given out to spouses of patients with a dementia diagnosis, at the end of clinic appointments by the memory nurse. Prior to the advertisement of the study, the researcher will meet with the memory nurses to give an overview of the study and also details of any inclusion and exclusion criteria.

Therefore, participants will choose to opt-in to the research study and the researcher will not be aware of participant details until they contact the researcher. Potential participants can contact the researcher via email, mobile telephone or complete the expression of interest form for the researcher to contact them. This initial contact does not assume consent to participate in the study, instead it is an opportunity for participants to ask the researcher more information about the study. At no point during or following completion of the study will staff from the memory service be aware of the identities of the participants. Therefore, no access to patient records will be required. Additionally, within the final write up of the study, participants will be referred to by an alternative so that they cannot be identified by memory service staff or other individuals.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

- Yes
- No

Please give details below:
No access to patient notes or data will be required.

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

- Yes
- No

If Yes, please give details of how and where publicity will be conducted, and enclose copy of all advertising material (with version numbers and dates).
Posters will be displayed within three memory clinics from the North-West region (within the same NHS trust) asking for participation from spouses whose partner has a diagnosis of Alzheimer's disease, vascular or mixed dementia. Therefore, participants will choose to opt-in to the research study and the researcher will not be aware of participant details until they contact the researcher.

A29. How and by whom will potential participants first be approached?

Participants will opt in to the study either by completing the expression of interest form, emailing or telephoning the lead researcher. If potential participants complete the expression of interest form, the lead researcher will contact them on the telephone number they have provided and discuss their potential participation in the study.
A30-1. Will you obtain informed consent from or on behalf of research participants?

☐ Yes ☐ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

All participants will be over eighteen years of age and able to provide informed consent. Prior to providing consent, participants will be sent a copy of the ‘Participant Information Sheet’ and will have the opportunity to ask the lead researcher questions about the study. Once participants are happy to take part in the study, prior to the start of the interview they will provide written consent via the ‘consent form’ which details exactly what they are consenting to.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

☐ Yes ☐ No

A31. How long will you allow potential participants to decide whether or not to take part?

Participants will have the length of time the interviews intend to run during the study (approximately 2-3 months) to decide if they wish to participate. All participants will be offered the opportunity to speak with the researcher via email, telephone or in person prior to consenting to take part in the study to discuss their potential participation.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? (e.g. translation, use of interpreters)

Unfortunately, interpreters will not be used for the purposes of this study. However, participants who require face to face meetings with the researcher to discuss their participation in the study.

Additionally, the information about the study will be given to participants via the information sheet.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? Tick one option only.

☐ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.

☐ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.

☐ The participant would continue to be included in the study.

☐ Not applicable – informed consent will not be sought from any participants in this research.

☐ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

If a participant was to lose capacity prior to the interview being conducted, no specific data would have been collated and they would therefore be withdrawn from the study with no data utilised. However, if a participant lost capacity following the completion of the interview and had previously consented to participate, the data would still be included in the study.

If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform
participants about this when seeking their consent initially.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? (Tick as appropriate)

- Access to medical records by those outside the direct healthcare team
- Access to social care records by those outside the direct social care team
- Electronic transfer by magnetic or optical media, email or computer networks
- Sharing of personal data with other organisations
- Export of personal data outside the EEA
- Use of personal addresses, postcodes, faxes, emails or telephone numbers
- Publication of direct quotations from respondents
- Publication of data that might allow identification of individuals
- Use of audio/visual recording devices
- Storage of personal data on any of the following:
  - Manual files (includes paper or film)
  - NHS computers
  - Social Care Service computers
  - Home or other personal computers
  - University computers
  - Private company computers
  - Laptop computers

Further details:
If participants choose to complete the 'expression of interest form' they will be asked to provide a contact telephone number on which the researcher can contact them about the study. The telephone number would be used for this purpose only and will be destroyed by the researcher once the participant has either taken part in the study or asked not to take part.

Within the write-up of this study direct quotes will be utilised as part of the results. However, all participants will be referred to by an alternative name and the overall results will be comprised of quotes from all participants, not individuals participants.

All interviews will be recorded using audio recording devices, which participants will contact to being used. The data recorded will be transferred at the soonest opportunity to an encrypted and password protected laptop, which only the lead researcher has access to. Once transferred all of the audio recordings will then be deleted from the recording device.

A38. How will you ensure the confidentiality of personal data? Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.

All participants will be referred to throughout the research by their alternative name, which they will create themselves. The researcher will also be mindful of participants not being identifiable through individual characteristics (e.g. age, length of relationship) in the final write-up of the study.
A40. Who will have access to participants’ personal data during the study? Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.

Other than the lead researcher, the academic supervisor, who is not employed by the NHS, will have access to participant’s data. The academic supervisor will listen to the first recorded interview and check the transcripts. Participants will be made aware of this prior to the start of the interview. All interactions between the researcher and participants on the day of the interview will be recorded including issues about consent.

Storage and use of data after the end of the study

A43. How long will personal data be stored or accessed after the study has ended?

- Less than 3 months
- 3 – 6 months
- 6 – 12 months
- 12 months – 3 years
- Over 3 years

*If longer than 12 months, please justify:*
The interview recordings will be destroyed after the completion of the final research paper. However, the transcripts developed from this will be stored on the university’s virtual private network for up to 10 years as per Lancaster University policy.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

- Yes
- No

*If Yes, please give details. For monetary payments, indicate how much and on what basis this has been determined.*
Participants can claim up to £20 travel expenses for the purposes of the interview. The research will provide expense forms to participants during the interview if necessary.

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

- Yes
- No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

- Yes
- No

NOTIFICATION OF OTHER PROFESSIONALS
A49. Will you inform the participants’ General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

- [ ] Yes
- [ ] No

*If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.*

**PUBLICATION AND DISSEMINATION**

A50. Will the research be registered on a public database?

- [ ] Yes
- [ ] No

*Please give details, or justify if not registering the research.*

The researcher intends to submit this research for publication in a peer reviewed journal, therefore the abstract and potentially full research paper will be publicly accessible on the publisher’s website.

*Registration of research studies is encouraged wherever possible.*

You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A51.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- [x] Peer reviewed scientific journals
- [ ] Internal report
- [ ] Conference presentation
- [x] Publication on website
- [ ] Other publication
- [ ] Submission to regulatory authorities
- [ ] Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- [ ] No plans to report or disseminate the results
- [ ] Other (please specify)

A53. Will you inform participants of the results?

- [ ] Yes
- [ ] No

*Please give details of how you will inform participants or justify if not doing so.*

Participants can choose to have a copy of the final report if they choose so. In this case, they would provide a copy of their address to the researcher, which will be kept in a sealed envelope separate to the transcripts and research data. Any personal data will be destroyed following the relevant correspondence.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? *Tick as appropriate:*

- [ ] Independent external review
- [ ] Review within a company
- [ ] Review within a multi−centre research group
Review within the Chief Investigator’s institution or host organisation
Review within the research team
Review by educational supervisor
Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
The research design and protocol will be reviewed by the researcher’s academic supervisor, prior to the review undertaken by the NHS Research Ethics Committee (REC). The academic supervisor will provide only advice and guidance on the design and follow through of the study. As part of the research work on the Clinical Psychology Doctoral programme, the results will be presented to other students and staff on the course. This will allow for the results to be disseminated to other individuals working within Clinical Psychology and also an opportunity for feedback before the paper is submitted for publication.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/institution.

A59. What is the sample size for the research? How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.

Total UK sample size: 10  
Total international sample size (including UK): 10  
Total in European Economic Area: 10

Further details:  
The study will aim to recruit 10 participants, however a minimum of six will be required in order for inferences and subsequent recommendations to be made from the data.

A60. How was the sample size decided upon? If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.

The sample size was chosen in order to provide a sample large enough for adequate qualitative data to be obtained. Smith, Flowers and Larkin (2009) suggest that between four and 10 participants is an adequate amount for professional doctorate research projects. This is so the data can be adequately interpreted and themes to be developed across participant data, without large amounts of data making the process overwhelming.

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

The transcribed data will be analysed using IPA which aims to explore the experiences of participants and how they make sense of their current situation. The emphasis of this approach is for the researcher to become emerged in the participants’ psychological world, which includes their beliefs, identity and own constructs of the world they live in (Smith, 2003). The verbatim accounts of participants will be transcribed and analysed using IPA (Smith et al., 2009). This particular analytic process is described as an iterative and inductive approach that involves six flexible stages.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator’s team, including non-doctoral student researchers.

<table>
<thead>
<tr>
<th>Title</th>
<th>Forename/Initials</th>
<th>Surname</th>
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<tbody>
<tr>
<td>Dr</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post</td>
<td>Clinical Psychologist</td>
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</tr>
</tbody>
</table>
Qualifications | BSc Psychology, Masters Degree, PhD and Doctorate in Clinical Psychology
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Employer | 
Work Address | 
Post Code | 
Telephone | 
Fax | 
Mobile | 
Work Email | 

### A64. Details of research sponsor(s)

#### A64-1. Sponsor

**Lead Sponsor**

Status:  
- [ ] NHS or HSC care organisation
- [ ] Academic
- [ ] Pharmaceutical industry
- [ ] Medical device industry
- [ ] Local Authority
- [ ] Other social care provider (including voluntary sector or private organisation)
- [ ] Other

*If Other, please specify:*

**Contact person**

Name of organisation: Lancaster University

Given name | 
Family name | 
Address | Lancaster University
Town/city | Lancaster
Post code | LA1 4YT
Country | UNITED KINGDOM
Telephone | 01524 592605
Fax | 
E-mail | ethics@lancaster.ac.uk

**Is the sponsor based outside the UK?**

- [ ] Yes  
- [x] No

*Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.*
A65. Has external funding for the research been secured?

☐ Funding secured from one or more funders
☐ External funding application to one or more funders in progress
☒ No application for external funding will be made

What type of research project is this?

☒ Standalone project
☐ Project that is part of a programme grant
☐ Project that is part of a Centre grant
☐ Project that is part of a fellowship/ personal award/ research training award
☐ Other

Other – please state:

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

☐ Yes  ☐ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68. Give details of the lead NHS R&D contact for this research:

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Details can be obtained from the NHS R&D Forum website: [http://www.rdforum.nhs.uk](http://www.rdforum.nhs.uk)

A69. How long do you expect the study to last in the UK?

Planned start date: 01/02/2016
Planned end date: 31/08/2016
Total duration:
Years: 0  Months: 6  Days: 31
### A71. Where will the research take place? *(Tick as appropriate)*

- England
- Scotland
- Wales
- Northern Ireland
- Other countries in European Economic Area

Total UK sites in study: 3

**Does this trial involve countries outside the EU?**
- Yes
- No

### A72. Which organisations in the UK will host the research? *Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

- NHS organisations in England: 1
- NHS organisations in Wales
- NHS organisations in Scotland
- HSC organisations in Northern Ireland
- GP practices in England
- GP practices in Wales
- GP practices in Scotland
- GP practices in Northern Ireland
- Joint health and social care agencies (e.g., community mental health teams)
- Local authorities
- Phase 1 trial units
- Prison establishments
- Probation areas
- Independent (private or voluntary sector) organisations
- Educational establishments
- Independent research units
- Other (give details)

Total UK sites in study: 1

### A76. Insurance/ indemnity to meet potential legal liabilities

**Note:** in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland

### A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

**Note:** Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.
### A76-2. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? Please tick box(es) as applicable.

**Note:** Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

<table>
<thead>
<tr>
<th>Option</th>
<th>Details</th>
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<tr>
<td>☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)</td>
<td>Other insurance or indemnity arrangements will apply (give details below)</td>
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<tr>
<td>✔</td>
<td>Lancaster University legal liability cover will apply.</td>
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Please enclose a copy of relevant documents.

### A76-3. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

**Note:** Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

<table>
<thead>
<tr>
<th>Option</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>✔ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)</td>
<td>Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)</td>
</tr>
</tbody>
</table>

Please enclose a copy of relevant documents.
**PART C: Overview of research sites**

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.

<table>
<thead>
<tr>
<th>Research site</th>
<th>Investigator/ Collaborator/ Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institution name</td>
<td>[Redacted]</td>
</tr>
<tr>
<td>Department name</td>
<td>[Redacted]</td>
</tr>
<tr>
<td>Street address</td>
<td>[Redacted]</td>
</tr>
<tr>
<td>Town/city</td>
<td>[Redacted]</td>
</tr>
<tr>
<td>Post Code</td>
<td>[Redacted]</td>
</tr>
</tbody>
</table>
# PART D: Declarations

## D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.

5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.

7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.

9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
   - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
   - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
   - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
   - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
   - May be sent by email to REC members.

10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.

11. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee’s final opinion or the withdrawal of the application.

**Contact point for publication** *(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

- [ ] Chief Investigator
Access to application for training purposes (Not applicable for R&D Forms)
Optional – please tick as appropriate:

☐ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Miss Rachel Blackburn on 17/02/2016 13:41.

Job Title/Post: Trainee Clinical Psychologist
Organisation: Lancaster University
Email: r.blackburn2@lancaster.ac.uk
D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.

2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.

3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.

4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.

   Please note: The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.

7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publicly accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by an authorised approver at ethics@lancaster.ac.uk on 08/03/2016 15:56.

Job Title/Post: Research Support Officer
Organisation: Lancaster University
Email: [redacted]
D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

**Academic supervisor 1**

This section was signed electronically by on 08/03/2016 13:08.

Job Title/Post: [Redacted]
Organisation: Lancaster University
Email: [Redacted]
08 April 2016

Mrs Rachel Watterson
Clinical Psychology, Division of Health Research
Lancaster University
Lancaster
LA1 4YT

Dear Mrs Watterson

<table>
<thead>
<tr>
<th>Study title:</th>
<th>Understanding self-conscious emotions: How partners of individuals with vascular or Alzheimer’s dementia feel about themselves</th>
</tr>
</thead>
<tbody>
<tr>
<td>REC reference:</td>
<td>*********</td>
</tr>
<tr>
<td>IRAS project ID:</td>
<td>189244</td>
</tr>
</tbody>
</table>

Thank you for your letter responding to the Proportionate Review Sub-Committee’s request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Assistant *********.

Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion
The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).


Where a NHS organisation’s role in the study is limited to identifying and referring potential participants to research sites (“participant identification centre”), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see “Conditions of the favourable opinion” above).
Approved documents

The documents reviewed and approved by the Committee are:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copies of advertisement materials for research participants</td>
<td>1</td>
<td>17 February 2016</td>
</tr>
<tr>
<td>Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)</td>
<td>1</td>
<td>11 March 2016</td>
</tr>
<tr>
<td>GP/consultant information sheets or letters [GP Letter]</td>
<td>1</td>
<td>06 April 2016</td>
</tr>
<tr>
<td>Interview schedules or topic guides for participants [Interview Schedule]</td>
<td>1</td>
<td>17 February 2016</td>
</tr>
<tr>
<td>IRAS Checklist XML [Checklist_11032016]</td>
<td></td>
<td>11 March 2016</td>
</tr>
<tr>
<td>IRAS Checklist XML [Checklist_06042016]</td>
<td></td>
<td>06 April 2016</td>
</tr>
<tr>
<td>Letters of invitation to participant [Expression of Interest]</td>
<td>1</td>
<td>17 February 2016</td>
</tr>
<tr>
<td>Other [Insurance 2]</td>
<td>1</td>
<td>11 March 2016</td>
</tr>
<tr>
<td>Other [Insurance 3]</td>
<td>1</td>
<td>11 March 2016</td>
</tr>
<tr>
<td>Other [Response Letter]</td>
<td>1</td>
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<tr>
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<td>Participant consent form [Consent Form]</td>
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<tr>
<td>Participant information sheet (PIS) [Participant Info Sheet]</td>
<td>3</td>
<td>04 April 2016</td>
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<tr>
<td>REC Application Form [REC_Form_09032016]</td>
<td></td>
<td>09 March 2016</td>
</tr>
<tr>
<td>Research protocol or project proposal [Protocol]</td>
<td>2</td>
<td>04 April 2016</td>
</tr>
<tr>
<td>Summary CV for Chief Investigator (CI) [CI CV]</td>
<td>1</td>
<td>17 February 2016</td>
</tr>
<tr>
<td>Summary CV for supervisor (student research) [Supervisor CV]</td>
<td>1</td>
<td>17 February 2016</td>
</tr>
</tbody>
</table>

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the
feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance

We are pleased to welcome researchers and R & D staff at our NRES committee members’ training days – see details at http://www.hra.nhs.uk/hra-training/

Please quote this number on all correspondence

With the Committee’s best wishes for the success of this project.

Yours sincerely

Dr Helen Brittain (Chair)

Email: NRESCommittee.WestMidlands-CoventryandWarwick@nhs.net

Enclosures:

“After ethical review – guidance for researchers”

Copy to: Ms Debbie Knight, Merseycare NHS Trust
Appendix 4

Mrs Rachel Watterson
Clinical Psychology, Division of Health Research
Lancaster University
Lancaster
LA1 4YT
06 July 2016

Dear Mrs Watterson,

Letter of HRA Approval for a study processed through pre-HRA Approval systems

Study title: Understanding self-conscious emotions: How partners of individuals with vascular or Alzheimer’s dementia feel about themselves
IRAS project ID: 189244
Sponsor: Lancaster University

Thank you for your request for HRA Approval to be issued for the above referenced study.

I am pleased to confirm that the study has been given HRA Approval. This has been issued on the basis that the study is compliant with the UK wide standards for research in the NHS.

The extension of HRA Approval to this study on this basis allows the sponsor and participating NHS organisations in England to set-up the study in accordance with HRA Approval processes, with decisions on study set-up being taken on the basis of capacity and capability alone.

If you have submitted an amendment to the HRA between 23 March 2016 and the date of this letter, this letter incorporates the HRA Approval for that amendment, which may be implemented in accordance with the amendment categorisation email (e.g. not prior to REC Favourable Opinion, MHRA Clinical Trial Authorisation etc., as applicable).

It is not expected that any other NHS organisations in England will participate in this study. If subsequent NHS organisations in England are added, an amendment should be submitted to the HRA, providing a Statement of Activities and Schedule of Events, upon which a full HRA assessment will be undertaken.
Participation of NHS Organisations in England

Please note that full information to enable set up of participating NHS organisations in England is not provided in this letter, on the basis that activities to set up these NHS organisations is likely to be underway already.

The sponsor should provide a copy of this letter, together with the local document package and a list of the documents provided, to participating NHS organisations in England that are being set up in accordance with HRA Approval Processes. It is for the sponsor to ensure that any documents provided to participating organisations are the current, approved documents.

It is critical that you involve both the research management function (e.g. R&D office and, if the study is on the NIHR portfolio, the LCRN) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

After HRA Approval

In addition to the document, “After Ethical Review – guidance for sponsors and investigators”, issued with your REC Favourable Opinion, please note the following:

1. HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
2. Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the After Ethical Review document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
3. The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please email the HRA at hra.approval@nhs.net. Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.
HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/.

If you have any queries about the issue of this letter please, in the first instance, see the further information provided in the question and answer document on the HRA website.

Your IRAS project ID is 189244. Please quote this on all correspondence.

Yours sincerely

Paul Mills
Research Management and Regulation Specialist
Email: hra.approval@nhs.net

Copy to:
Appendix 5

Notice of Amendment

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select ‘Save’ and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Self-conscious emotions in partners of people with dementia

1. Is your project research?
   - Yes
   - No

2. Select one category from the list below:
   - Clinical trial of an investigational medicinal product
   - Clinical investigation or other study of a medical device
   - Combined trial of an investigational medicinal product and an investigational medical device
   - Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
   - Basic science study involving procedures with human participants
   - Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
   - Study involving qualitative methods only
   - Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
   - Study limited to working with data (specific project only)
   - Research tissue bank
   - Research database

If your work does not fit any of these categories, select the option below:
   - Other study

2a. Please answer the following question(s):
   a) Does the study involve the use of any ionising radiation?
      - Yes
      - No
   b) Will you be taking new human tissue samples (or other human biological samples)?
      - Yes
      - No
   c) Will you be using existing human tissue samples (or other human biological samples)?
      - Yes
      - No

3. In which countries of the UK will the research sites be located? (Tick all that apply)
☐ England
☐ Scotland
3a. In which country of the UK will the lead NHS R&D office be located:

- England
- Scotland
- Wales
- Northern Ireland
- This study does not involve the NHS

4. Which applications do you require?

**IMPORTANT:** If your project is taking place in the NHS and is led from England select ‘IRAS Form’. If your project is led from Northern Ireland, Scotland or Wales select ‘NHS/HSC Research and Development Offices’ and/or relevant Research Ethics Committee applications, as appropriate.

- IRAS Form
- NHS/HSC Research and Development offices
- Social Care Research Ethics Committee
- Research Ethics Committee
- Confidentiality Advisory Group (CAG)
- National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D Offices in Northern Ireland, Scotland and Wales the CI must create NHS/HSC Site Specific Information forms, for each site, in addition to the study wide forms, and transfer them to the PIs or local collaborators.

For participating NHS organisations in England different arrangements apply for the provision of site specific information. Refer to IRAS Help for more information.

5. Will any research sites in this study be NHS organisations?

- Yes
- No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or a Diagnostic Evidence Co-operative in all study sites?

Please see information button for further details.

- Yes
- No

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

- Yes
- No

The NIHR Clinical Research Network provides researchers with the practical support they need to make clinical studies happen in the NHS e.g. by providing access to the people and facilities needed to carry out research “on the ground”.
If you select yes to this question, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) immediately after completing this project filter question and before submitting other applications. Failing to complete the PAF ahead of other applications e.g. HRA Approval, may mean that you will be unable to access NIHR CRN Support for your study.

6. Do you plan to include any participants who are children?

- **Yes**
- **No**

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

- **Yes**
- **No**

*Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.*

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

- **Yes**
- **No**

9. Is the study or any part of it being undertaken as an educational project?

- **Yes**
- **No**

*Please describe briefly the involvement of the student(s):*

The lead researcher (Rachel Blackburn) is currently enrolled on the Clinical Psychology Doctoral programme at Lancaster University. The lead researcher will be supervised by both Lancaster University staff and NHS staff.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

- **Yes**
- **No**

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

- **Yes**
- **No**

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

- **Yes**
- **No**
NOTICE OF SUBSTANTIAL AMENDMENT

Please use this form to notify the main REC of substantial amendments to all research other than clinical trials of investigational medicinal products (CTIMPs).
The form should be completed by the Chief Investigator using language comprehensible to a lay person.

Details of Chief Investigator:

Title  Forename/Initials  Surname
Mrs Rachel Watterson

Work Address  Clinical Psychology, Division of Health Research
             Lancaster University
             Lancaster

PostCode  LA1 4YT
Email  r.watterson@lancaster.ac.uk
Telephone  01524 592970
Fax

For guidance on this section of the form refer to the guidance

Full title of study:  Understanding self-conscious emotions: How partners of individuals with vascular or Alzheimer's dementia feel about themselves

Lead sponsor:  Lancaster University

Name of REC:  

REC reference number:  

Additional reference number(s):

Ref.Number Description   Reference Number

Name of lead R&D office:  

Date study commenced:  22nd August 2016

Protocol reference (if applicable), current version and date:  Version 3, 18.10.16

Amendment number and date:  Amendment 1, 18.10.16

Type of amendment

(a) Amendment to information previously given in IRAS

☐ Yes  ☐ No

If yes, please refer to relevant sections of IRAS in the “summary of changes” below.
In ‘participants’ section of protocol method, it was previously stated that only individuals whose partner has a diagnosis of Alzheimer’s disease, vascular or mixed dementia would be included in the study. However, I now wish to expand this criteria to people whose partner has a diagnosis of any type of dementia. Therefore, the title of the research paper has removed the words to ‘Alzheimer’s or vascular’ to reflect the inclusion of all types of dementia.

(b) Amendment to the protocol

Yes ☐ No ☐

If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

See amended protocol, version 3, dated 18.10.16.

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study

Yes ☐ No ☐

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

Is this a modified version of an amendment previously notified and not approved?

Yes ☐ No ☐

Summary of changes

Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study. If this is a modified amendment, please explain how the modifications address the concerns raised previously by the ethics committee.

If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

The original inclusion criteria of this study was to include only partners of people living with a diagnosis of Alzheimer’s disease, vascular or mixed dementia. However, it is now proposed that the inclusion criteria will be expanded to include partners of people living with any type of dementia. It is anticipated that widening this criteria will provide more participants with the opportunity to share their experiences and take part in the study. Additionally, as the interviews are focused upon the experiences of the partner, rather than the person living with dementia, it is not anticipated that the type of dementia will have a significant impact on the partner’s experience. Furthermore, all participants will continue to be recruited from the same memory service and therefore will have access to similar service provisions and support.

Any other relevant information

Applicants may indicate any specific issues relating to the amendment, on which the opinion of a reviewing body is sought.

List of enclosed documents

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
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<td>Protocol_RW_V3_181016_Tracked</td>
<td>3</td>
<td>18/10/2016</td>
</tr>
<tr>
<td>Protocol_RW_V3_181016</td>
<td>3</td>
<td>18/10/2016</td>
</tr>
</tbody>
</table>

Declaration by Chief Investigator
I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.

I consider that it would be reasonable for the proposed amendment to be implemented.

This section was signed electronically by Miss Rachel Blackburn on 18/10/2016 21:14.

Job Title/Post: Trainee Clinical Psychologist
Organisation: Lancaster University
Email: r.blackburn2@lancaster.ac.uk

Declaration by the sponsor’s representative

I confirm the sponsor’s support for this substantial amendment.

This section was signed electronically by An authorised approver at ethics@lancaster.ac.uk on 26/10/2016 09:45.

Job Title/Post: 
Organisation: 
Email: 


Appendix 6

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

25 November 2016

Mrs Rachel Watterson
Clinical Psychology, Division of Health Research
Lancaster University
Lancaster
LA1 4YT

Dear Mrs Watterson,

| Study title: | Understanding self-conscious emotions: How partners of individuals with vascular or Alzheimer’s dementia feel about themselves |
| REC reference: | 16/WM/0154 |
| Amendment number: | Substantial Amendment 1, 18.10.16 |
| Amendment date: | 18 October 2016 |
| IRAS project ID: | 189244 |

The above amendment was reviewed on 25 November 2016 by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:
Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members’ training days – see details at [http://www.hra.nhs.uk/hra-training/](http://www.hra.nhs.uk/hra-training/): 

Please quote this number on all correspondence

Yours sincerely

PP

E-mail: 

Enclosures: 
List of names and professions of members who took part in the review

Copy to: 

### Attendance at Sub-Committee of the REC meeting on 25 November 2016

#### Committee Members:

<table>
<thead>
<tr>
<th>Name</th>
<th>Profession</th>
<th>Present</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Helen Brittain</td>
<td>Clinical Psychologist</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Karen Schofield</td>
<td>Retired Consultant, Haematologist</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

#### Also in attendance:

<table>
<thead>
<tr>
<th>Name</th>
<th>Position (or reason for attending)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teagan Allen</td>
<td>REC Assistant</td>
</tr>
<tr>
<td>Daniella Sarno</td>
<td>REC Assistant</td>
</tr>
</tbody>
</table>
Appendix 7

IRAS 189244. SA 1. HRA Assessment Amendment Outcome
AMENDMENTS, Hra (HEALTH RESEARCH AUTHORITY)
[hra.amendments@nhs.net]

To:
Blackburn, Rachel; Ethics (RSO) Enquiries
Cc:

Dear Mrs Watterson,

Further to the below, I am pleased to confirm that HRA Approval has been issued for the referenced amendment, following assessment against the HRA criteria and standards.

The sponsor should now work collaboratively with participating NHS organisations in England to implement the amendment as per the below categorisation information. This email may be provided by the sponsor to participating organisations in England to evidence that the amendment has HRA Approval.

Please contact hra.amendments@nhs.net for any queries relating to the assessment of this amendment.

Yours sincerely

Beverley

Beverley Mashegede |
Assessor
Health Research Authority
Nottingham
HRA Centre, The Old Chapel, Royal Standard Court, Nottingham NG1 6FS
E: beverleymashegede@nhs.net | T: 02071048065 | www.hra.nhs.uk
Appendix 8

Consent Form

‘Understanding self-conscious emotions: How partners of people living with dementia feel about themselves’

Before you consent to participating in the study we ask that you read the participant information sheet and mark each box below with your initials if you agree. If you have any questions or queries before signing the consent form please speak to the principal investigator, Rachel Watterson.

1. I confirm that I have read the information sheet and fully understand what is expected of me within this study.

2. I confirm that I have had the opportunity to ask any questions and to have them answered.

3. I understand that my interview will be audio recorded and then made into an anonymised written transcript. I understand that audio recordings will be kept until the research project has been examined.

4. I understand that after consenting to take part in the study, I can choose to withdraw up to two weeks after my interview has been conducted. If I choose to withdraw up to this point my interview data will be destroyed and not used in the final study; however if I choose to withdraw after this point my data will remain in the study.

5. I understand that the information from my interview will be pooled with other participants’ responses, anonymised and may be published.

6. I consent to information and quotations from my interview being used in reports, conferences and training events.

7. I understand that any information I give will remain strictly confidential and anonymous unless it is thought that there is a risk of harm to you, myself or others. In this case the principal investigator may need to share this information with the

Please initial box after each statement

☐  ☐  ☐  ☐  ☐  ☐  ☐
appropriate emergency services and the supervisors of the project, even without my consent.

8. I consent to Lancaster University keeping written transcriptions of the interview for 10 years after the study has finished.

9. I consent for a letter to be sent to my GP informing them of my participation in the study.

10. I consent to take part in the above study.

Name of Participant__________________ Signature__________________ Date __________

Name of Researcher__________________ Signature__________________ Date __________
Appendix 9

Participant Information Sheet

‘Understanding self-conscious emotions: How partners of individuals with dementia feel about themselves’

My name is Rachel Watterson and I am conducting this research as a trainee clinical psychologist at Lancaster University, Lancaster.

What is the study about?

The purpose of this study is to explore how you feel about yourself as a partner of someone with a diagnosis of dementia. Additionally, the study will explore if there are differences in how you felt about yourself prior to and now following your partner’s diagnosis of dementia.

It is anticipated that this information will develop our current understanding of the emotional experiences of partners, which may impact upon their psychological and physical wellbeing. Furthermore, these findings aim to inform the type of support systems which should be in place around the individual with dementia and their partner. The findings may also inform the pathway for future research in this area.

Why have I been approached?

You have been approached because the study requires information from individuals who currently live with their partner and who has had a diagnosis of dementia for at least two years. For the
purposes of this research the term partner refers to individuals who have lived with and have been in a relationship with an individual with dementia for five years prior to the dementia diagnosis.

Do I have to take part?
No. It’s completely up to you to decide whether or not you take part, there is no obligation. You can contact the lead researcher, Rachel Watterson, via telephone or complete the expression of interest form so that the lead researcher can contact you if you have any questions or queries regarding participating in the research.

What will I be asked to do if I take part?
If you decide you would like to take part, you would be asked to read and sign a consent form, detailing the requirements of your participation. The lead researcher will contact you to arrange a suitable time to meet at your local memory clinic or GP surgery for an interview; alternatively home visits can be arranged if this is more suitable. The interview will last around an hour although this can be shorter or longer depending on what you wish to discuss and any other commitments you have. The interview will discuss the emotions you have and this will constitute as your participation in the study.

Will my data be confidential?
The information you provide is confidential, unless you disclose information that puts you or other people at risk. You will also be asked to create an alternative name for yourself, which you will be referred by throughout the research project. Additionally, the lead researcher will ensure that you cannot be identified from the information you give in the final write up of the study.
The following steps will also be taken to ensure that the information you provide is protected and remains confidential.

- During the undertaking of the project, the transcripts will be saved in password protected documents and stored electronically on the university’s Virtual Private Network (VPN).
- All paper documents (e.g. consent forms) will be locked in a secure cabinet, only accessible by the lead researcher.
- Upon completion of the project all paper documents will be destroyed by the lead researcher.
- Other than the lead researcher, only the academic supervisor, who is not employed by the NHS, of the project will have access to the anonymised transcripts while the project is being conducted. Additionally, the academic supervisor will listen to the audio recording of the first interview providing that your name is not included.
- All personal participant information will be confidential and participants’ details will be anonymised. This includes the transcribed version of your interview being made anonymous by removing any personally identifying information such as your name. Anonymised direct quotations from your interview may be used in the reports or publications from the study, but your name will not appear in the final write up or publications.

There are some limits to confidentiality: if what is said in the interview makes me think that you, or someone else, is at significant risk of harm, I will have to break confidentiality and potentially inform the emergency services.

**What will happen to the results?**
The results will be summarised and reported in a thesis research project for Lancaster University, Doctorate in Clinical Psychology course and will be submitted for publication in a peer-reviewed academic journal.

**Can I withdraw from the study?**

After consenting to take part in the study, you can choose to withdraw up to two weeks after your interview has been conducted. If you choose to withdraw up to this point your interview data will be destroyed and not used in the final study; however if you choose to withdraw after this point your data will remain in the study.

**Are there any risks?**

There are no risks anticipated with participating in this study. However, if you experience any distress following participation you are provided with the contact details for several resources at the end of this sheet. Additionally, with your permission the researcher will send a letter to your GP informing them of your participation so that they can provide any additional support you may require.

**Are there any benefits to taking part?**

Although you may find participating interesting and the results may contribute to the development of support provisions within memory and older adult services, there are no direct benefits in taking part.

**Who has reviewed the project?**

This study has been reviewed by [RESEARCH ETHICS COMMITTEE] Research Ethics Committee. Research ethics committee appraise all projects conducted within the NHS. However, should you need to
submit a complaint about the study, please contact Professor Bruce Hollingsworth at Lancaster University on the below contact details.

Where can I obtain further information about the study if I need it?

If you have any questions about the study, please contact the main researcher:

Rachel Watterson
Address: Clinical Psychology, Division of Health Research, Lancaster University, Lancaster, LA1 4YT Phone: 07508406248 Email: r.watterson@lancaster.ac.uk

Complaints

If you wish to make a complaint or raise concerns about any aspect of this study and do not want to speak to the researcher, you can contact:

[Redacted] Lancaster University Head of the Division of Health Research,
Tel: (01524) 592127
Email: [Redacted]
Faculty of Health and Medicine (Division of Health Research) Furness Building Lancaster University Lancaster LA1 4YG

Thank you for taking the time to read this information sheet.
Resources in the event of distress

Should you feel distressed either as a result of taking part, or in the future, the following resources may be of assistance. You should also speak to your GP should you feel distressed or require mental health support.

The Carers Trust Sefton Carers Centre 27-37 South Road Waterloo L22 5PE 0151 288 6060
www.seftoncarers.org.uk

Living Well Centre 25-35 Scarisbrick Avenue Southport PR8 1NW 0151 288 6890
www.livingwellcentre.org.uk

Carers Project Local Solutions Mount Vernon Green Hall Lane Liverpool L7 8TF
www.localsolutions.org.uk/projects/carers/

Alzheimer’s Society www.alzheimers.org.uk

National Dementia Helpline 0300 222 11 22
Appendix 10

Expression of Interest Form

‘Understanding self-conscious emotions: How partners of individuals with dementia feel about themselves’

I would like to express an interest in participating in the above research. I provide my consent for the principal investigator, Rachel Watterson, to contact me on the details that I have provided below, to discuss my participation in the project further. I understand that by completing this form, I am not consenting to participating in the study. It is a no obligation expression of my interest.

Name of potential participant:

Contact telephone number:

Signature: _______________________________________

Date: ___________________________________________
Dear Dr

Re:   D.O.B:

I am writing to inform you that the above patient has participated in the following research;

‘Understanding self-conscious emotions: How partners of individuals with dementia feel about themselves.’

This study has been reviewed by [Omitted Research Ethics Committee]. While there are no anticipated risks with participating in this study, participants have been provided with the contact details for their local carers centre and Alzheimer’s Society. Additionally, participants have been encouraged to seek support from their GP should they experience any distress or require additional support following participation in the study.

Yours Sincerely

Rachel Watterson

Trainee Clinical Psychologist
Appendix 12

Interview Schedule

‘Understanding self-conscious emotions: How partners of individuals with dementia feel about themselves’

- Background to research; purpose and structure of interview; issues of confidentiality and consent; sign consent form; any questions. Ask age of participant and partner, how long they have been in relationship (years), length of time living together (years) current support systems in place (informal and formal) and how long since diagnosis (months) (approx. 5 minutes)

Pre-diagnosis (approx. 20 minutes):

- What did you do before you cared for your partner?
- What were you like as a person then?
- How would you describe how you felt about yourself prior to your partner’s diagnosis? (I.e. laid back, critical, compassionate, positive/negative, accomplished, proud, not good enough)
- Were you happy with feeling like this or would have liked to change the way you felt about yourself?
- How would you have felt towards yourself when you had achieved something or other people had recognised you doing something well? Were you comfortable feeling like this?
- How would you have felt towards yourself when you thought you had made a mistake or something had not gone well for you? How did you cope with this?
• Where there differences in your how you felt about yourself and how you felt about other people? I.e. more critical of self or more critical of others? If so, why?

Post-diagnosis (approx. 40 minutes):

• Has caring for your partner changed you as a person? If it has, how?
• Can you compare yourself to how you were before you cared for your partner?
• How would you describe your general attitude towards yourself since to your partner’s diagnosis? (I.e. laid back, critical, compassionate, positive/negative). Why do you think this has/not changed since diagnosis?
• Does this change depending on the situation you were in or is it mainly consistent? Could you give me an example?
• Would you like to change how you feel about yourself? In what way?
• Do you think this helps when dealing with difficult situations? If so, how? Example?
• How do you feel towards yourself when you achieve something or other people recognise you do something well? Are you more/less comfortable feeling like this than previously?
• How do you have feel about yourself when you think you have made a mistake or something has not gone well for you? How do you cope with this?
• Do you think this affects your relationships with other people, in particular your partner? Example?
• Do you think this affects any other aspect of your functioning? (E.g. motivation, being goal driven, mood, keep up with hobbies and interest).

Is there anything else you would like to add about how you feel about yourself?
Interested in taking part in research?

- Has your partner had a diagnosis of dementia for more than two years?
- Do they live at home with you?
- If yes, would you be willing to be interviewed about your experiences of how you feel about yourself as a partner of someone with dementia?

- Contact the researcher directly:

Rachel Watterson

r.watterson@lancaster.ac.uk       Phone: 07508406248

Or request an Expression of Interest form from your memory nurse