

Section 4: Ethics

Laurence Regan

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Doctorate in Clinical Psychology

Faculty of Health and Medicine

Division of Health research

Lancaster University

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FHMREC Application

Faculty of Health and Medicine Research Ethics Committee (FHMREC) Lancaster University

Application for Ethical Approval for Research involving direct contact with human participants

Instructions **[for additional advice on completing this form, hover PC mouse over 'guidance']**

1. Apply to the committee by submitting:
 - a. The University's **Stage 1 Self Assessment (part A only)** and the **Project Questionnaire**. These are available on the Research Support Office website: [LU Ethics](#)
 - b. The completed application **FHMREC form**
 - c. Your full research proposal (background, literature review, methodology/methods, ethical considerations)
 - d. All accompanying research materials such as, but not limited to,
 - 1) Advertising materials (posters, e-mails)
 - 2) Letters/emails of invitation to participate
 - 3) Participant information sheets
 - 4) Consent forms
 - 5) Questionnaires, surveys, demographic sheets
 - 6) Interview schedules, interview question guides, focus group scripts
 - 7) Debriefing sheets, resource lists

Please note that you DO NOT need to submit pre-existing handbooks or measures, which support your work, but which cannot be amended following ethical review. These should simply be referred to in your application form.

2. Submit all the materials electronically as a **SINGLE email attachment in PDF format** by the deadline date. **Before converting to PDF ensure all comments are hidden by going into 'Review' in the menu above then choosing show markup>balloons>show all revisions in line.**
3. Submit one collated and signed paper copy of the full application materials in time for the FHMREC meeting. If the applicant is a student, the paper copy of the application form must be signed by the Academic Supervisor.
4. Committee meeting dates and application submission dates are listed on the [FHMREC website](#). Applications must be submitted by the deadline date, to:

Dr Diane Hopkins
B14, Furness College
Lancaster University,
LA1 4YG
d.hopkins@lancaster.ac.uk
5. Prior to the FHMREC meeting you may be contacted by the lead reviewer for further clarification of your application.
6. Attend the committee meeting on the day that the application is considered, if required to do so.

1. **Title of Project:** The views of people with Huntington's disease on assisted dying: A qualitative study

2. **Name of applicant/researcher:** Laurence Regan

3. Type of study

- Includes *direct* involvement by human subjects.
- Involves existing documents/data only, or the evaluation of an existing project with no direct contact with human participants. Please complete the University Stage 1 Self Assessment part B. This is available on the Research Support Office website: [LU Ethics](#). Submit this, along with all project documentation, to Diane Hopkins.

4. If this is a student project, please indicate what type of project by marking the relevant box: (please note that UG and taught PG projects should complete **FHMREC form UG-tPG**, following the procedures set out on the [FHMREC website](#))

PG Diploma Masters dissertation DClInPsy SRP PhD Thesis PhD Pall. Care
 PhD Pub. Health PhD Org. Health & Well Being PhD Mental Health MD
 DClInPsy Thesis

Applicant Information

5. **Appointment/position held by applicant and Division within FHM** Trainee Clinical Psychologist

6. **Contact information for applicant:**

E-mail: l.regan@lancaster.ac.uk **Telephone:** (please give a number on which you can be contacted at short notice)

Address: Clinical Psychology, Faculty of Health and Medicine, Furness College, Lancaster University, Lancaster, LA1 4YG

7. **Project supervisor(s), if different from applicant:** Dr Jane Simpson

8. **Appointment held by supervisor(s) and institution(s) where based (if applicable):** Research Director, Doctorate in Clinical Psychology, Furness College, Lancaster University, Lancaster, LA1 4YT

9. **Names and appointments of all members of the research team (including degree where applicable)**

Laurence Regan, MSc
 Dr Jane Simpson, DClInPsy, PhD
 Dr Nancy Preston, PhD

The Project

NOTE: In addition to completing this form you must submit a detailed research protocol and all supporting materials.

10. **Summary of research protocol in lay terms (indicative maximum length 150 words):**

Assisted dying is not legal in the UK, however it is frequently the topic of public discussion around end-of-life issues for people with advanced progressive diseases. As a result of the genetic heritability of Huntington's disease (HD), people affected have a unique awareness in advance that they will severely decline in physical and cognitive functioning and will have often witnessed a parent or other relative experience such decline. People with HD can experience low mood, anxiety and other psychological difficulties and have been found to be at increased risk of suicide. No studies have explored the views and beliefs of people with HD about the concept of assisted dying. This study aims to use thematic analysis to understand the views and concerns of people with HD. Six to ten participants will be interviewed about their views on the legal status of assisted dying and their beliefs about assisted dying and advanced care planning, drawing on their personal experiences of having a life-limiting illness. It may also provide insight into how to integrate assisted dying usefully into the care of patients with HD, were it made legal.

11. **Anticipated project dates (month and year only)**

Start date: September 2015

End date: June 2016

12. Please describe the sample of participants to be studied (including maximum & minimum number, age, gender):

Between six (minimum) and ten (maximum) participants will be recruited. Participants will have a self-reported confirmed diagnosis of Huntington's disease or be pre-symptomatic gene positive. Therefore, all participants will have undergone genetic testing and possess the requisite cytosine-adenine-guanine (CAG) repeat expansion on the huntingtin gene. Participants will also be aged 18 or over. There will be no upper age limit or restrictions on gender.

Non-English speakers who would require an interpreter due to financial restraints will be excluded. Individuals whose symptoms (such as cognitive impairment) are severe enough to make interview impossible will also be excluded, although reasonable adjustments will be made to promote inclusivity. It is expected that participants will be either pre-symptomatic or have begun to experience symptoms but are at an early stage of the disease course.

13. How will participants be recruited and from where? Be as specific as possible.

The study will recruit through the Huntington's Disease Association England & Wales and use a purposive sampling technique. This may be done through their mailing list as well as via adverts on social media (for example, their site message board, Facebook group or Twitter). The Huntington's Disease Association England & Wales will therefore share information about the study (participant information sheet) on my behalf without requiring use of personal social media. People who are interested in taking part will be able to contact Laurence directly for more information or opt in to take part in the research. Potential participants would be able to contact Laurence directly via email or university mobile. Potential participants would have the option to leave a voicemail message expressing interest.

When a participant makes contact via one of the methods outlined above, Laurence will then contact the potential participant to explain more about the study and to answer any questions. If participants are still interested an interview will be arranged. At opt in potential participants would be asked questions over telephone to identify whether they meet the inclusion and exclusion criteria.

At opt in potential participants will be intentionally screened to ensure they have heard of assisted dying and would be happy to offer their opinions on the topic with reference to their own experiences. If potential participants have not heard of assisted dying, it will be explained to them at this stage. If they are not comfortable talking about this issue with reference to their own experiences then they would be thanked for their interest and informed that due to the focus of the research it would not be appropriate to interview them. In this way the sample will be purposive.

14. What procedure is proposed for obtaining consent?

Verbal consent to send further information about the study will be obtained at opt in. After opting in participants will be sent the participant information sheet (Appendix A) to ensure they have time to consider the information prior to interview. A person must be assumed to have capacity until it is established that s/he lacks capacity (British Psychological Society, 2005). Capacity will therefore be assumed, although it is recognised that potential participants' ability to consent may be impacted by how someone is cognitively affected by HD. Laurence will consider capacity to consent on an individual basis and purposively select participants based on clinical judgement and the Mental Capacity Act (Appendix B). At interview, the researcher will discuss consent and confidentiality with the participants and provide the information sheet (Appendix A) and consent form (Appendix C) for the participant to sign. Written informed consent will be obtained at this stage. Subsequent to this demographic information will be obtained, including date of birth, gender, ethnic group, marital status and whether participants have children. It will be explained to the participant that they may withdraw their participation, or their data, at any point before thesis submission. If the request to withdraw comes after analysis has begun, every attempt will be made to extract the data, up to the point of thesis submission.

15. What discomfort (including psychological eg distressing or sensitive topics), inconvenience or danger could be caused by participation in the project? Please indicate plans to address these potential risks. State the timescales within which participants may withdraw from the study, noting your reasons.

Participants will be asked questions about their experiences that inform their views about assisted dying. There is therefore a risk that participants will become distressed talking about this sensitive issue. Prior to giving informed consent, participants will be informed about sensitive topics arising in the interview. Participants will be informed before commencing the interview that they may take a break or stop at any time if needed. Sensitivity to participants' anxiety levels and language skills will be monitored throughout each interview to ensure inclusive practice (Perry, 2004). Participants' cognitive abilities will be responded to by adapting questions accordingly. Laurence, who will be conducting the interviews, has experience of working with people who are distressed and accordingly will use his clinical expertise to address distress sensitively and appropriately, should distress arise during the course of interviews. They will also be signposted to appropriate support services should they feel distressed as a result of interview, such as the Huntington's Disease Association England & Wales (which will be an existing network of support for participants) and the Samaritans. Participants will be made aware of limits of confidentiality in the Participant Information Sheet and also prior to the start of the interview. Namely, that any concerns (risk to self or others) will be discussed with the research supervisor and if necessary information will be passed on to the appropriate people, for example, other health professionals (such as the individual's general practitioner) regarding concerns about their own safety or the police. If there are any concerns that need to be shared, for example a risk issue like current intent to harm themselves or others, this will be discussed with the participant if possible and they will be reminded of limitations to confidentiality. Although interviews are not anticipated to cause significant distress, in the event that a participant finds interview significantly distressing they will be encouraged to see a member of their direct care team to discuss this as well as their link worker at the Huntington's Disease Association England & Wales.

16. What potential risks may exist for the researcher(s)? Please indicate plans to address such risks (for example, noting the support available to you; counselling considerations arising from the sensitive or distressing nature of the research/topic; details of the lone worker plan you will follow, and the steps you will take).

Interviews will take place at an appropriate and convenient place of the participant's choosing. If a public venue is chosen, this will be contacted before interview to ensure safety and appropriateness (i.e. that there is a suitable location for a confidential interview). When conducting home visits, the researcher will adhere to Lancaster University Guidance on Safety in Fieldwork policy, as outlined in the University's document Guidance on safety in fieldwork (<http://www.lancaster.ac.uk/depts/safety/files/Fieldwork.pdf>). A sealed envelope with information of the name and location of the participant, expected start and finish time, and transport/vehicle details of the researcher will be given to an appointed contact (a colleague who is part of the research team). Laurence will contact the appointed contact involved in the study prior to the interview taking place, and on its completion. Where this telephone call does not happen, attempts will be made to contact the interviewer. If contact cannot be made within agreed and reasonable timescales, local escalation procedures for alerting their senior manager or the police will be carried out.

17. Whilst we do not generally expect direct benefits to participants as a result of this research, please state here any that result from completion of the study.

Although participants may find participating interesting, there are no direct benefits in taking part. This research will contribute to the evidence base for assisted dying and Huntington's disease.

18. Details of any incentives/payments (including out-of-pocket expenses) made to participants:

Participants will not be provided with incentives or payments for taking part in the study.

19. Briefly describe your data collection and analysis methods, and the rationale for their use. Please include details of how the confidentiality and anonymity of participants will be ensured, and the limits to confidentiality.

This is a qualitative study which will use semi-structured interviews to gather data. The interviews will follow an interview schedule which will allow flexibility in questioning to allow the researcher to follow issues which are most important to the participant. This will allow for the naturalistic emergence of themes relevant to participants and reduce interviewer influence on the content of the data. A phenomenological approach to the data will be taken. Accordingly, responses from participants will be understood to be their subjective realities rather than one truth within their accounts. An inductive approach will be taken whereby the data will be analysed without trying to fit it into any pre-existing coding. The five steps of thematic analysis as outlined by Braun and Clarke (2006) will be used. An idiographic approach to the data will be taken, with the first interview analysed in detail before moving onto the next, case by case. Each transcript will be read and re-read to increase familiarity with and immersion in the data. The transcripts will be systematically annotated, with points of interest or particular significance made. Then these items will be examined and emerging themes will be identified. A summary list of themes, based on all the transcripts, will be constructed and super-ordinate themes will be obtained. The transcripts will be constantly re-examined to ensure that the themes still relate to the original texts. The analysis will focus on sensitivity to context, rigour, coherence, transparency and importance: core principles of validity and quality in qualitative research (Yardley, 2008). Laurence will conduct the transcription of the interviews.

Participants will be made aware of limits of confidentiality in the Participant Information Sheet and also prior to the start of the interview. If there are any concerns which need to be shared, for example a risk issue if a participant were to indicate that they may cause harm to themselves or others, this will be discussed with the participant. Any concerns will be discussed with the research supervisor and if necessary information will be passed on to the appropriate people, for example, other health professionals regarding concerns about their own safety or the police.

Skype is an alternative method of conducting interviews to face to face. Since Skype interviews are not wholly secure, this will be made clear to participants who choose this method, and they will be reminded of this at the start of the Skype interview.

20. If relevant, describe the involvement of your target participant group in the *design and conduct* of your research.

Members of the HDA were consulted at the design stage of research to ensure that interview questions were sensitive and appropriate.

21. What plan is in place for the storage of data (electronic, digital, paper, etc.)? Please ensure that your plans comply with the Data Protection Act 1998.

The electronic data will be encrypted and stored on a password protected computer. The files will be backed up on an encrypted USB device. Computer files of the transcripts and the original recordings will be deleted after write up of the research. In accordance with the Data Protection Act 1998, all data will be encrypted and saved electronically, including consent forms which will be scanned and saved, and then stored by the Research Coordinator in password-protected file space on the university server. The data will be kept for ten years in the event of a request for the raw data of the study in accordance with University and DClInPsy programme policy. The Research Coordinator will have responsibility for the storage and deletion of this data after the Laurence has completed the DClInPsy programme.

22. Will audio or video recording take place? no audio video

If yes, what arrangements have been made for audio/video data storage? At what point in the research will tapes/digital recordings/files be destroyed?

A digital Dictaphone will be used to record interviews. Interviews will be transcribed as soon as possible after interview and stored on a secure (password-protected) computer. Interviews and transcripts shared with the

supervisory team will be anonymised to ensure participants are not identifiable. Audio recordings will be deleted from the Dictaphone as soon as they have been transferred to a computer. The Dictaphone will be securely transported in a locked bag and stored in the meantime in a locked cabinet. The reason for earliest possible upload of audio recordings is that it is likely not possible to encrypt the portable device. The Research Coordinator will have responsibility for the storage and deletion of this data after the Laurence has completed the DClinPsy programme.

Data on portable devices will be encrypted; if it cannot be encrypted any identifiable data (including recordings of participants' voices) will be deleted from the recorder as soon as possible (i.e. when it has been transferred to a password protected computer) and in the meantime the recorder will be stored securely.

23. What are the plans for dissemination of findings from the research? If you are a student, include here your thesis.

The research will be submitted for the thesis assignment as part of the Laurence's doctorate in clinical psychology programme at Lancaster University. The results of the research will also be submitted for publication in an academic/professional journal. This will be disseminated to the HDA.

24. What particular ethical considerations, not previously noted on this application, do you think there are in the proposed study? Are there any matters about which you wish to seek guidance from the FHMREC?

Signatures: Applicant:L. Regan.....

Date:13.05.15.....

*Project Supervisor

.....

Date:



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*I have reviewed this application, and discussed it with the applicant. I confirm that the project methodology is appropriate. I am happy for this application to proceed to ethical review.

Research Protocol**The views of people with Huntington's disease on assisted dying: A qualitative study****Applicants*****Principal Investigator***

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Introduction

Huntington's disease (HD) is a genetic neurodegenerative condition characterised by motor and coordination problems and cognitive impairment. HD is an inherited condition, caused by an increased number of trinucleotide repeats in the coding region of the huntingtin gene (Kirkwood, Su, Conneally, & Foroud, 2001). This mutation is autosomal dominant so each child of an affected person has a 50% chance of inheriting it. HD is unique in this respect, as individuals with a diagnosis will usually have seen a parent affected by the condition. Kay, Fisher and Hayden (2014) suggest that around five to ten in 100,000 people of European descent are affected. Symptoms vary between individuals but disease trajectory is predictable; during the condition's later stages, the person typically has dementia, marked decline in physical and cognitive functioning and as a result is totally dependent and requires full nursing care.

Many people at various stages of HD (including those who carry the gene but are pre-symptomatic) experience emotional difficulties (e.g. Paulsen et al., 2001, Julien et al., 2007, Craufurd & Snowden, 2014). It is frequently presumed that biological factors are the main determinants of psychological distress in people with HD and the majority of research in this area is quantitative. However, research in this area has shown that psychological factors such as illness beliefs and coping mechanisms play a major role in people's mental health and wellbeing (e.g. Kaptein et al., 2006; Arran, Craufurd and Simpson, 2013).

Age of diagnosis is typically around 35-55, although physical symptoms may emerge at any time throughout the life span and life expectancy from time of diagnosis is approximately 20 years (Walker, 2007). One area of concern is whether end-of-life care for people with HD is managed adequately (McGarva, 2001; Simpson, 2007). Adema et al. (2010) examined four cases in the Netherlands between 2006 and 2009 where patients with HD requested euthanasia. The researchers reported that people's fear of going through the same process

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as close relatives plays a role in their emotional distress and expectations.

Upcoming admission to a nursing home was seen as a turning point, as all patients were still living at home. Fear of cognitive decline, total dependency and being unable to give meaning to life were important issues for patients. Congruently, a cross-sectional study by Di Maio (1993) reviewed the National HD research roster in the United States of America, where euthanasia is not legal, and found that suicide was the most reported cause of death in people with HD (7.3% completed and up to 27% attempted), much more frequent than in the general population (estimated at .013%).

Due to the decline in cognitive ability as a result of HD it can be difficult to comprehend a person's wishes at the end of life. Advance care planning is considered an intrinsic part of end-of-life care and consideration of its use is recommended for any adult with capacity with a life-limiting condition (Henry & Seymour, 2008). In England and Wales an advance refusal of treatment is legally binding for adults aged over 18 years who have the mental capacity to make the decision (Department of Health, 1999). However, an advance directive only applies to the refusal of medical treatment. The clinical decision to administer treatment lies with the physician and not with the individual. Accordingly, it is not possible to use an advance directive to make a statement relating to the treatment an individual would like to receive. So although people with HD may indicate clear choices about attempts to prolong life, such as refusing resuscitation at the time of death, they are not able to direct which treatments are administered to them.

Lord Falconer's Assisted Dying Bill, which was tabled in the House of Lords in 2014, argues that the law should allow terminally ill, mentally competent adults to request life-ending medication from a doctor. The dying patient would then have the choice to self-administer that medication at a time that was right for them. If this Bill were to be passed in the UK assisted dying would potentially be an important discussion to be had around advanced care planning. Media documentaries and newspaper reports have provided significant coverage of issues of assisted dying/euthanasia. However, research in this area often focuses on the views of medical professionals, families and carers. Limited evidence suggests that people who have life-limiting conditions generally favour assisted dying. For example, Chapple, Ziebland, McPherson and Herxheimer's (2006) study on the views of people with a 'terminal illness' on euthanasia and assisted suicide found that most participants thought that UK law should change to allow assisted dying. Participants who had seen others die held particularly strong beliefs in an individual's 'right to die'.

Despite being widely advocated, advance care directives are infrequently used (Barnes, Jones, Tookman and King, 2007). The reason for this is unclear, as doctors and patients seem to be favourably disposed to advance directives. For example, a survey of outpatients found that advance care directives were desired by 93% of participants (Emanuel, Barry, Stoeckle, Ettelson, & Emanuel, 1991). Research also demonstrates beneficial outcomes for care from the use of advance care directives. A randomised controlled trial by Detering, Hancock, Reade, & Silvester (2010) found that advance care planning improved end of life care and patient and family satisfaction and reduced stress, anxiety, and depression in surviving relatives compared to care as usual. It is noteworthy that there is significant debate about whether or not the availability of assisted dying is beneficial or harmful in those countries where it has been legalised. However, in lieu of alternatives UK residents are resorting to measures such as travelling to other countries, such as Switzerland, to die with assistance or ending their own lives.

There has not previously been research exploring the views and beliefs of people with HD about the concept of assisted dying. It is not known whether they feel it could improve their care, and if so how. This lack of empirical research provides the rationale for the proposed study. The data gathered from the proposed study could identify the concerns of

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those who might be most likely to make requests for assisted dying. It may also provide insight into how to integrate assisted dying usefully into the care of patients with HD, were it made legal. This issue is timely and appropriate to explore given the increased rates of suicide associated with HD and the public discussion around end-of-life issues for people with advanced progressive diseases. It is particularly important within this population because of the hereditary nature of HD and the fact that individuals with the disease may have witnessed a parent experience significant decline and death. They will be acutely aware in advance that their ability to communicate and their cognitive function will become impaired.

Research aim & objectives

The overarching aim of this research is to explore the views of people with HD on assisted dying within the context of their own lived experiences.

Within this, the research has a number of specific questions: to explore people's views on advanced care directives and to develop an understanding of views on the acceptability and legal status of assisted dying regarding its relevance to HD.

Method

Design

Qualitative approaches are particularly suited to research which focuses on understanding processes rather than outcomes (Smith, 2007). Braun and Clarke (2006) recognise that qualitative methodologies allow for the possibility of generating rich, complex data. I am interested in understanding the perceptions and experiences of people with HD and in order to illuminate richness and detail a thematic analysis was chosen. After opting in participants will be sent the participant information sheet (Appendix A) to ensure they have time to consider the information prior to interview. After opt in, participants with HD will be contacted to arrange a semi-structured interview, to be conducted by Laurence Regan (chief investigator). Interviews will take place at the participant's home or at a community venue convenient to the participant (e.g. local library or community centre). It is anticipated that interviews will last approximately 1 hour, but may take place over more than one session if the participant becomes tired or requests this. If the participant prefers, interviews may also be conducted over the phone or over the internet (e.g. using Skype). Participants will be made aware that Skype is encrypted but not completely secure.

Participants

Small sample sizes are valued in qualitative research. Sandelowski (1995) suggests that an analysis of fewer participants at greater depth is preferable to a shallow and merely descriptive examination of many. Therefore, this study aims to recruit between six and ten participants.

Inclusion criteria:

- Participants will have a self-reported confirmed diagnosis of HD or be pre-symptomatic gene positive. Therefore, they all participants will have undergone genetic testing and possess the requisite cytosine-adenine-guanine (CAG) repeat expansion on the huntingtin gene.
- Participants will also be aged 18 or over.

Exclusion criteria:

- Non-English speakers who would require an interpreter due to financial restraints.
- Individuals whose symptoms (such as cognitive impairment) are severe enough to make interview impossible, although reasonable adjustments will be made to promote inclusivity. It is expected that participants will be either pre-symptomatic

or have begun to experience symptoms but are at an early stage of the disease course.

Procedure

Recruitment

The study will recruit through the Huntington's Disease Association England & Wales and use a purposive sampling technique. This may be done through their mailing list as well as via adverts on social media (for example, their site message board, Facebook group or Twitter). People who are interested in taking part will be able to contact Laurence directly via email or university mobile for more information or opt in to take part in the research.

When a participant makes contact via one of the methods outlined above, Laurence will then contact the potential participant to explain more about the study and to answer any questions. If participants are still interested an interview will be arranged. At opt in potential participants would be asked questions over telephone to identify whether they meet the inclusion and exclusion criteria.

At opt in potential participants will be intentionally screened to ensure they have heard of assisted dying and would be happy to offer their opinions on the topic with reference to their own experiences. If potential participants have not heard of assisted dying, it will be explained to them at this stage. If they are not comfortable talking about this issue with reference to their own experiences then they would be thanked for their interest and informed that due to the focus of the research it would not be appropriate to interview them. In this way the sample will be purposive.

Interviews

After opt-in, participants will be contacted to arrange a semi-structured interview, to be conducted by Laurence Regan. Interviews will take place at the participant's home or at a community venue convenient to the participant (e.g. local library or community centre). At interview, the researcher will discuss consent and confidentiality with the participants and provide an information sheet (Appendix B) and consent form (Appendix C) for the participant to sign. Written informed consent will be obtained at this stage. It will be explained to the participant that they may withdraw their participation, or their data, at any point before thesis submission. If the request to withdraw comes after analysis has begun, every attempt will be made to extract the data, up to the point of thesis submission. It is anticipated that interviews will last approximately one hour but may take place over more than one session if the participant becomes tired or requests this. If the participant prefers, interviews may also be conducted over the phone or over the internet (e.g. using Skype). Interviews will use a topic guide (see Appendix D). Interviews will be transcribed by Laurence as soon as possible after interview and stored on a secure computer. The interviews will be transcribed verbatim with any identifiable information anonymised. Sensitivity to participants' anxiety levels and language skills will be monitored throughout each interview to ensure inclusive practice (Perry, 2004).

Analysis

The aim of the research is to provide a thematic description of the data. Therefore, an inductive approach will be taken whereby the data will be analysed without trying to fit it into any pre-existing coding. The five steps of thematic analysis as outlined by Braun and Clarke (2006) will be used; (1) familiarising self with the data, (2) generating initial codes, (3) searching for themes, (4) reviewing themes, and (5) defining and naming themes.

Emerging themes will be discussed with the research supervisor and field supervisor in order to reduce researcher bias and optimise the reliability of the analysis.

An idiographic approach to the data will be taken, with the first interview analysed in detail before moving onto the next, case by case. Each transcript will be read and re-read to increase familiarity with and immersion in the data. The transcripts will be systematically annotated, with points of interest or particular significance made. Then these items will be examined and emerging themes will be identified. A summary list of themes, based on all the transcripts, will be constructed and super-ordinate themes will be obtained. The transcripts will be constantly re-examined to ensure that the themes still relate to the original texts. The analysis will focus on sensitivity to context, rigour, coherence, transparency and importance: core principles of validity and quality in qualitative research (Yardley, 2008). Research supervision will be valuable at this stage to check the reliability of analysis and ensure that the most relevant data are retained in the final themes.

Dissemination

The research will be submitted for the thesis as part of the Laurence's doctorate in clinical psychology programme at Lancaster University. The results of the research will also be submitted for publication in a relevant academic journal. Participants will also receive a copy of the findings and the results will be disseminated to the HDA.

Practical issues

Digital audio recordings will be deleted from the Dictaphone as soon as they have been transferred to a computer. The Dictaphone will be securely stored in the meantime. The computer files will be encrypted and password protected. The files will be backed up on an encrypted USB device. Computer files of the transcripts will be deleted after write up of the research. Hard copies of the anonymised transcripts will be stored securely at Lancaster University in accordance with the Data Protection Act 1998. The data will be kept for five years in the event of a request for the raw data of the study. Interviews and transcripts shared with the supervisors will be anonymised to ensure participants are not identifiable.

All costs of photocopying, printing and freepost envelopes will be covered by Lancaster University. If participants incur travelling costs to take part in the research they will be reimbursed up to £10 in accordance with Lancaster University policy.

Ethical issues

Ethical approval for the study will be sought from the Research Ethics Committee at Lancaster University.

Risk to researchers

When conducting home visits, the researcher will adhere to Lancaster University Guidance on Safety in Fieldwork policy, as outlined in the University's document Guidance on safety in fieldwork (<http://www.lancaster.ac.uk/depts/safety/files/Fieldwork.pdf>). A sealed envelope with information of the name and location of the participant, expected start and finish time, and transport/vehicle details of the researcher will be given to an appointed contact (a colleague who is part of the research team). Laurence will contact the appointed contact involved in the study prior to the interview taking place, and on its

completion. Where this telephone call does not happen, attempts will be made to contact the interviewer. If contact cannot be made, the appropriate authorities will be informed.

Risk of psychological distress to participants

The interview schedule will focus upon participants' general attitudes toward the acceptability and legal status of assisted dying and its relevance for Huntington's disease. It is not anticipated to cause significant distress. However, participants will be asked questions about their experiences that inform their views. They may bring up how the topic relates to their personal situation (for example, envisaging future circumstances in which they would personally request euthanasia) but this will not be a central focus of the interview. There is therefore a risk that participants will become distressed talking about this sensitive issue. Prior to giving informed consent, participants will be informed about the possibility of sensitive topics arising in the interview. Participants will be informed before commencing the interview that they may take a break or stop at any time if needed. Laurence, who will be conducting the interviews, has experience of working with people who are distressed and accordingly will use his clinical expertise to address distress sensitively and appropriately, should distress arise during the course of interviews. They will also be signposted to appropriate support services should they feel distressed as a result of interview.

Anticipated timeframe for research

December 2014: submit thesis proposal form and gain feedback

January 2015: review proposal form and address feedback

January - March 2015: Finalise method

May - June 2015: Agree timetable/ Contract with supervisory team

May - July 2015: Prepare protocol

August - September: Ethical review

October - December: Data collection/ Literature Review

December 2015: 1st draft literature review

December 2015 - March 2016: Data analysis

February 2016: Literature review 2nd draft

March 2016: Research paper 1st draft

April 2016: Research paper 2nd draft

April 2016: Critical Appraisal 1st draft

May 2016: Critical appraisal 2nd draft

May 2016: Thesis hand in

References

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Appendix 4-A**The views of people with Huntington's disease on assisted dying: A qualitative study****Participant Information Sheet**

My name is Laurence Regan, I am a trainee clinical psychologist at Lancaster University. I am conducting a research project as part of my Doctoral training exploring the views of people with Huntington's disease (HD) on assisted dying. I will be conducting interviews with people with HD, which would last up to an hour.

What is the study about?

This study aims to understand people's views on assisted dying, its legality, how it could affect their care, and their personal situations and how this affects their views.

Why have I been approached?

You have been approached because I think you could provide important insights and valuable information about the experiences and views of people with HD. Some people who offer to take part may not be included in the study, if they would not be able to talk about their experiences and their views about assisted dying.

Do I have to take part?

No. It's completely up to you to decide whether or not you take part or not.

What will I be asked to do if I take part?

If you decide you would like to take part, we would arrange a time and date for interview that suits you. The interview is likely to take up to an hour. You would be asked about your views on assisted dying and your experiences that inform these views. It can take place over more than one session if you would prefer. Interviews may be face-to-face, via telephone or Skype. If face-to-face is chosen it will take place at a suitable location of your choice (such as your home or a quiet venue local to you). It is important to note that although Skype is encrypted it is not wholly secure.

Who can take part?

Anyone who has a confirmed diagnosis of HD can take part who is over the age of 18 and can speak English to a sufficient level to be able to take part in the interviews. This means you will have undergone genetic testing and have a confirmed diagnosis of Huntington's disease or be pre-symptomatic gene positive.

What will you do with the information I give you?

The interview will be recorded and transcribed. The original recordings will be destroyed after they have been written up and the transcripts will be securely stored. Everything you say will be kept confidential. Direct quotes may be used but all identifiable information will be anonymised. The only time I would have to break confidentiality is if there were an issue of risk to yourself or others, in which case information may need to be passed on to appropriate people. If this were to happen I would tell you if possible.

Will my data be confidential?

The information you provide is confidential. The data collected for this study will be stored securely and only the researchers conducting this study will have access to this data:

- Audio recordings will destroyed and/or deleted after they have been analysed.
- Hard copies of consent forms will be kept in a locked cabinet.

ETHICS

- The files on the computer will be encrypted (that is no-one other than the researcher will be able to access them) and the computer itself password protected.
- At the end of the study, hard copies of forms will be kept securely in a locked cabinet for five years. At the end of this period, they will be destroyed.
- The typed version of your interview will be made anonymous by removing any identifying information including your name. Anonymised direct quotations from your interview may be used in the reports or publications from the study, so your name will not be attached to them.

What if I change my mind?

You're welcome to change your mind at any time and there is no pressure on you to continue. There is no time limit for changing your mind, although once your data has been anonymised and incorporated into themes it might not be possible for it to be withdrawn. However, every attempt will be made to extract my data, up to the point of thesis submission.

What will happen to the results?

The results will be summarised and reported in a dissertation/thesis and will also be submitted for publication in an academic or professional journal. The findings will also be disseminated to the Huntington's Disease Association England and Wales.

Are there any risks?

There are no risks anticipated with participating in this study. However, if you experience any distress following participation you are encouraged to inform the researcher and contact the resources provided at the end of this sheet.

Are there any benefits to taking part?

Although you may find participating interesting, there are no direct benefits in taking part. This research will contribute to the evidence base for assisted dying and Huntington's disease.

Who has reviewed the project?

This study has been reviewed by the Faculty of Health and Medicine Research Ethics Committee, and approved by the University Research Ethics Committee at Lancaster University.

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:
l.regan@lancaster.ac.uk, [phone number]

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:

Prof Roger Pickup, Associate Dean for Research, Faculty of Health and Medicine (Division of Biomedical and Life Sciences), Lancaster University, Lancaster LA1 4YD (email:
r.pickup@lancaster.ac.uk , Tel: (01524) 593746

If you wish to speak to someone outside of the Clinical Psychology Doctorate Programme, you may also contact:

Professor Paul Bates Tel: (01524) 593718
Associate Dean for Research Email: p.bates@lancaster.ac.uk
Faculty of Health and Medicine
(Division of Biomedical and Life Sciences)
Lancaster University
Lancaster

ETHICS
LA1 4YD

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:

The Samaritans (08457 909090) is an organisation that is available 24 hours a day to provide confidential emotional support for people who are experiencing feelings of distress, despair or suicidal thoughts.

Huntington's disease association www.hda.org.uk

There is lots of advice and information on their website. **If you call the head office on 0151 331 5444, they can put you in touch with your regional care advisory service. More information about this service is given here:** <http://hda.org.uk/hda/rca>

Appendix 4-B

The views of people with Huntington’s disease on assisted dying: A qualitative study

Capacity check form for researcher

Participant name:

(Circle the appropriate response and sign at the bottom of the sheet.)

1. I have given the information about the project to the potential participant.

Yes/No

2. I believe that they understand the information relevant to the decision.

Yes/No

3. I believe that the potential participant is able to weigh up information as a part of the process of making a decision.

Yes/No

4. Based on my clinical judgement this person does have the capacity to consent to taking part in the research project.

Yes/No

Signed

Appendix 4-C

 Lancaster University
 Doctoral Programme in Clinical Psychology

Thesis Consent Form

The views of people with Huntington's disease on assisted dying: A qualitative study

We are asking if you would like to take part in a research project looking at assisted dying. 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 chief investigator, Laurence Regan. Please initial box after each statement

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.	
4	I understand that audio recordings will be kept until the research project has been examined.	
5	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
6	I understand that once my data have been anonymised and incorporated into themes it might not be possible for it to be withdrawn, though every attempt will be made to extract my data, up to the point of publication.	
7	I understand that the information from my interview will be pooled with other participants' responses, anonymised and may be published	
8	I consent to information and quotations from my interview being used in reports, conferences and training events.	
9	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 myself or others, in which case the principal investigator may need to share this information with his research supervisor.	
10	I consent to Lancaster University keeping electronic transcriptions of the interview for 10 years after the study has finished.	
11	I consent to the recording and transcript of the interview being shared and discussed with the principal investigator's research supervisor.	
12	I consent to take part in the above study.	

Name of Participant _____ Signature _____ Date _____

Name of Researcher _____ Signature _____ Date _____

Appendix 4-D

The views of people with Huntington's disease on assisted dying: A qualitative study

Topic guide

This guide gives indication of the topic areas to be discussed in the interview with example questions. The precise questions will be dependent on participants' responses and the focus of each interview will be guided in part by what is deemed important to the individual being interviewed.

Introduction

Introduce self. Revisit participant information sheet and purpose of interview. Check any necessary demographic information not already collected at point of consent.

Example questions

"What is your understanding of assisted dying? "

"What are your thoughts on assisted dying? "

"It's not legal in the UK at the moment, what do you think about that? "

"Would you tell me about your Huntington's? "

"How does your Huntington's affect your views on assisted dying? "

"What do you think are the reasons behind some people wanting assisted dying? "

"Do you have any concerns about your end of life? "

"Would ever opt for assisted dying if it was legal and available? "

"Are there any situations in the future where you might opt for assisted dying?"

"Is there anything else you would like to tell me?"

Clarifying questions

Used to raise more detail/narrative of topics raised by initial and follow up questions. For example:

"You mentioned _____ can you tell me more about that?"

"Could you give me an example of that?"

"How does that make you feel?"

"How does that fit with [previous response]?"

Conclusion

In this part of the interview the participant will be thanked for taking part. The interviewer will ensure the participant has not been distressed by the interview and if necessary will direct the participant to sources of support on the participant information sheet.

Appendix 4-E
Research Poster



Do you have **Huntington's disease (HD)**? Do you have views about **assisted dying** and end-of-life care?

If so, please consider taking part in this study. I am interested in interviewing people with HD and exploring their views on the issue of assisted dying.

This research will contribute to our understanding of this important issue for people with Huntington's disease.

Participants must have a confirmed **diagnosis of HD**, be **18 or over** and **be able to speak English** to a sufficient level to be able to take part in the interviews. Interviews last around an hour and can be at a place of your choice.

If you have any questions about the study or would like to take part, please contact the main researcher, Laurence Regan:

l.regan@lancaster.ac.uk, 07508406276

More information at:

http://www.lancaster.ac.uk/shm/study/doctoral_study/dclinpsy/research/laurenceregan/

This study has been reviewed by the Faculty of Health and Medicine Research Ethics Committee, and approved by the University Research Ethics Committee at Lancaster University.

Appendix 4-F**Ethics Approval letter**

Applicant: Laurence Regan
Supervisor: Jane Simpson
Department: DHR
FHMREC Reference: FHMREC15026

16 November 2015

Dear Laurence

Re: Amendment to *The views of people with Huntington's disease on assisted dying: A qualitative study*

Thank you for submitting your research ethics amendment for the above project for review by the Faculty of Health and Medicine Research Ethics Committee (FHMREC). The application was recommended for approval by FHMREC, and on behalf of the Chair of the University Research Ethics Committee (UREC), I can confirm that approval has been granted for this research project.

As principal investigator your responsibilities include:

- ensuring that (where applicable) all the necessary legal and regulatory requirements in order to conduct the research are met, and the necessary licenses and approvals have been obtained;
- reporting any ethics-related issues that occur during the course of the research or arising from the research to the Research Ethics Officer (e.g. unforeseen ethical issues, complaints about the conduct of the research, adverse reactions such as extreme distress);
- submitting details of proposed substantive amendments to the protocol to the Research Ethics Officer for approval.

Please contact me if you have any queries or require further information.

☎ (01542 5)92838 ↪ fhmresearchsupport@lancaster.ac.uk)

Yours sincerely,



Diane Hopkins
Research Development Officer

CC Ethics@Lancaster; Professor Roger Pickup (Chair, FHMREC)