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)
Kinections- Strenthening community in care homes Version1.0

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

- [x] Scotland
- [ ] Wales
- [ ] Northern Ireland

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?

- [ ] NHS/HSC Research and Development offices
- [x] Research Ethics Committee
- [ ] Confidentiality Advisory Group (CAG)
- [ ] Her Majesty's Prison and Probation Service (HMPPS)

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

○ Yes ◉ No

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

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

Integrated Research Application System
Application Form for Research involving qualitative methods only

NHS Health Research Authority

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 familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Kinections- Strenthening community in care homes Version1.0

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

REC Name:
Kinections-strenthening community in care homes

REC Reference Number:
10-SS0020

Submission date:
17/01/2020

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Exploring and enhancing dementia-friendly communities in care homes using Appreciative Inquiry

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Dr	Anna	Jack-Waugh
Post	Lecturer Later Life and Dementia		
Qualifications	Prof.D, MSc, RNT, BSc (Hons), RMN.		
ORCID ID	0000 0002 5611 2218		
Employer	University of the West of Scotland		
Work Address	School of Health and Life Sciences, UWS Crichton Campus Bankend Road, Dumfries, DG14ZN		
Post Code	DG14ZN		
Work E-mail	anna.jack-waugh@uws.ac.uk		

* Personal E-mail	
Work Telephone	01387345800
* 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.

	Title	Forename/Initials	Surname
	Dr	W.Gordon	Mackay
Address	School of Health and Life Sciences		
	University of the West of Scotland		
	Stephenson Place		
Post Code	G720LH		
E-mail	w.mackay@uws.ac.uk		
Telephone	07828669984		
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):	N/A
Sponsor's/protocol number:	Project ID 4257
Protocol Version:	Version 2.
Protocol Date:	05/06/2018
Funder's reference number (enter the reference number or state not applicable):	Not applicable
Project website:	myhomelife.uws.ac.uk/scotland/kinections

Additional reference number(s):

Ref.Number Description	Reference Number

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.
This application is part of an ongoing study which up to this point has not been submitted to this review process as all participants have capacity to consent. Ethical approval to date has been through School of Health and Life Sciences, UWS Ethics Committee.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

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.*

It has been suggested that it is through investment in relationships in care homes that community is created (Davies and Brown-Wilson, 2007). However, as there is as yet an absence of an agreed understanding of what 'dementia-friendly community' means in the context of care homes, there is scope to deepen our understanding of the concept of community further as it applies in this setting.
The study is funded by Life Changes Trust/Big Lottery and involves 19 care homes in East Ayrshire. Phase 1 of Kinections began in February 2018 and is ongoing. This first phase is working with care home residents, staff, family and friends and the wider community. Phase 1 does not include people who lack capacity.

This proposal relates to Phase 2, which is seeking to include people with dementia living who lack capacity, up to a maximum of 15 people from one care home, with a completion date of October 2020.
The aim of Phase 2 of the study is to use observation as a method in the exploration and enhancement of dementia-friendly communities in care homes for people with advanced dementia.
Observation will be used to collect information on interactions between people which appear to build a connection with and understanding of the preferences, hopes and experiences of people with advanced dementia. In summary, this project aims to further generate new knowledge in terms of our understanding of how people with advanced dementia are part of their care home community.

The research method will be the observation of the person with dementia as they engage in social interactions and everyday care home activities. The researcher will carry out a maximum of 5 observations per person over a maximum 3 month period, with the average observation expected to last between 5-15 minutes.

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.

The over-arching ethical issue is with regard to observation of a person, in the context of a research study, who lacks capacity to give written consent.
The ethical issue centres on the person's right to a private life, and for their inclusion in a research study to be in line their wishes, as best these can be determined.

Consent as a Process
Ongoing consent monitoring, feedback and support will be established through a working partnership between the resident, care home staff, welfare guardian or nearest relative and researcher.

Assent and Dissent

Verbal cues and utterances, non-verbal gestures and any other behaviour or emotional signals will be the means by which information will be gathered as to the resident's assent or dissent. The researcher will work closely with the care home staff in gaining an understanding of how the person might usually express assent or dissent. Examples of indications of assent could include a verbal 'yes', nods, positive facial expressions. If the resident shows signs of stress or distress during the period of observation, the observation will be discontinued, while the person is experiencing stress/distress.

Consultation with others
When speaking with the welfare guardian/nearest relative, the researcher will ask if the resident has in the past expressed a view regarding participation in research. If no particular view has been expressed the researcher will ask the welfare guardian/nearest relative to consider if they think it likely that being involved in a study exploring community might be something that the resident would be agreeable to.

Observation and minimum necessary intrusion
In the first instance, the researcher will liaise with the care home manager/senior staff member on each occasion before engaging with residents who lack capacity. The researcher will at all times be sensitive to the fact that they are in the living space of residents and so will be mindful of being respectful and attuned to what is happening in the care home environment.

Public Space
While the observations will be taking place in a public space, the researcher will not be collecting any data on persons other than those for whom they have obtained consent.

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
- ☐ Metanalysis
- ☑ Qualitative research
- ☑ Questionnaire, interview or observation study
- ☐ Randomised controlled trial
- ☐ Other (please specify)

Social observation

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

A key objective of the study is to be inclusive of people experiencing all stages of dementia. This study is interested in exploring what being part of a dementia-friendly community means for people with advanced dementia who may not be able to articulate their experience verbally. This study would like to use the information gathered to work with people who live, visit and work in care homes in maximising opportunities for people living with dementia to be part of their care home community, in ways which matter to them.

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

To further develop the capacity of care home staff, residents, visiting family and friends, and interested wider community members to engage with residents with dementia, including residents with advanced dementia, to explore what matters to them and what community means to them.
To further develop the capacity care home staff, residents, family, friends and wider community members and groups to take forward ideas and actions that enable people with dementia living in care homes and those who support them to enjoy a sense of belonging in and contributing to the communities they value.
To celebrate the learning generated within the care home and share this learning locally, nationally and internationally.

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

The limited research to date which has been carried out on the topic of dementia-friendly communities has focused on issues such as environment and education and training. To date, we have not found any research which has specifically explored the experience of people with dementia (who lack capacity) in relation to dementia-friendly communities in care homes.

The Kinections project is novel in that it is taking a collaborative approach to the topic of dementia-friendly communities in care homes, by involving a wide range of people who live, visit and work in care homes.

The study is endeavouring to generate new knowledge on the concept of dementia-friendly communities in care homes as it pertains to people with advanced dementia and also on what helps positive practices to grow, develop and be as responsive as possible to people with dementia who live in care homes.

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.*

Appreciative Inquiry (AI) is the chosen methodology for this project. The approach has been successfully used in previous health and social care research projects (Dewar, 2011; Dewar et al., 2017; McBride., 2017; Roddy, 2017). AI uses a strengths-based approach, which recognises that everyone is the expert of their own experience and so within AI there is a focus on recognising everyone's expertise and using this information to work together to create an even better future. Appreciative inquiry involves focuses on identifying what people care about, what is working well and what people find energising. Conversations then aim to delve deeper into why these things are important and what the person values about them. This then creates the foundation for exploring possibilities for the future, to enable what the person values to be brought to life, in ways that may not previously have been considered. Out of this consideration of new future possibilities can emerge new ideas which can lead to new actions.

The number of participants will be up to 15 residents in one care home.

It is proposed that each person (resident) involved in observation in this study will be observed by the researcher in the following way
Where: in the person's (resident's) social environment as they spend time alone, with others or engage in activities in public spaces.

For how long: up to a maximum of 15 minutes
How many times: up to 5 times throughout a maximum of 3 months
What will the researcher be observing:
(i)The person's responses, verbal and non-verbal language when interacting with other residents/staff/visitors

(ii)The person's responses, verbal and non-verbal language when engaging in an everyday activity alone or with others, for example if the staff are showing photographs from a recent care home event

The researcher will be in the communal space during the time of observation- and will postpone writing up the field notes until they are in a private area.

The approach to what the researcher will focus on during the observation period will be informed by the Quality Interaction Schedule (Healthcare Improvement Scotland, 2012) and Caring Conversations Framework (Dewar, 2011).

An example of an observation might be where staff are engaging with the participant to find out what the person would like for their time in the social space, and how the participant responds to these engagements.
The data (field notes) will be examined for information of what might have helped this to be a positive experience.

The purpose of collecting data from observations is to share this information with others, for example the resident's family or staff, and explore how this information can affirm existing good practices, deepen people's knowledge about the person who has been observed and could be used to enhance further the experiences of those who live in care homes.

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

- [x] Management of the research
- [x] Undertaking the research
- [x] Analysis of results
- [x] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
Design of the Research: The initial proposal for the Kinections project (Spring 2017) was sense-checked by the Scottish Dementia Working Group (SDWG). At the time of proposal development, the group's work plan was full, and they were unable to commit to a 3-year timescale due to the nature of dementia. The project did receive the support of the SDWG for its participatory and inclusive ethos.
The design of this research study was informed by the extensive work of My Home Life in care homes across Scotland. Relatives of people living with dementia have been involved in My Home Life as members of the Steering Group and participants in research projects.

Management of the Research:
The research project is being led by the My Home Life team, in the School of Health and Life Science. The Project Team for Kinections involves people from Health and Social Care Partnership, people with experience of caring for relatives living with dementia, academics from the areas of health and community.

Undertaking the research:
Kinections endeavours to work with as wide a range as people from within care homes, and their local communities. These have included residents, visitors, community groups, creative groups, local advocacy service, Care Inspectorate and NHS staff.
Kinections has also established links with the local Alzheimer Scotland Dementia Resource Café.

Analysis of Results and Dissemination of Findings
The approach within this study is to engage in analysis and dissemination of findings from the very beginning of data generation. Hence, with people's permissions we are endeavouring to share people's stories on an ongoing basis, to as wide an audience as possible. This includes through a regular newsletter, social media, website and recent communication with local newspaper. My Home Life Scotland/UWS is part of an international movement called My Home Life, and so the findings of this study are also being shared among care homes across the UK, Germany and Australia.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

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

People living in one care home with a diagnosis of dementia who do not have the capacity to give consent to participate in research.

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

People who do not spend time in communal areas in which social observation would be possible
People who do not have a welfare guardian/ next of kin with whom we can consult regarding the resident's involvement in the study and who do not have relevant documentation, i.e. Section 47 certificate

RESEARCH PROCEDURES, RISKS AND BENEFITS

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.

Intervention or procedure	1	2	3	4
Social observation	5		1-15 mins	Researcher, Dr Edel Roddy. Previous experience of working in care homes as a registered nurse.

A21. How long do you expect each participant to be in the study in total?

Up to a maximum of 3 months.
The total duration of the observational phase of the study will be no greater than 3 months.
This length of time was chosen to ensure there was sufficient time to gather a number of observations on each resident involved- with the researcher visiting the home 2-4 times per month.

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.

There is the potential for it to be considered intrusive for the researcher to be engaging in observation in the participants' social spaces.

The researcher will introduce themselves to residents, explaining why they are in the care home. The researcher will continue to do this for as often as the resident wishes to know, for example, will repeat introductions if necessary.

As the interaction is social, there is likely to be a benefit as opposed to a burden.

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?

Being an active social member of a community may become more difficult for the person with dementia as their abilities to communicate verbally, initiate conversations or share activities are reduced by cognitive decline. Increasing experience of isolation and exclusion from social activities and the community may result.
As this project design is dynamic and responsive to the research findings, there is potential for a benefit to the participant to occur as an outcomes of an observation. For example, if the researcher notices something that appears to bring the resident satisfaction, a follow-on conversation with the care home staff may result in the source of satisfaction being integrated more often into their everyday experiences.

A26. What are the potential risks for the researchers themselves? *(if any)*

Risks to the researcher are minimal. The researcher will work collaboratively with care home staff and will draw on the staffs' expertise concerning the participants, to be sensitive to potential sources of stress or distress.

Care home staff members will be available when the researcher is engaged in the social observations as part of their usual duties and hence will be available to be called on if required.

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.

A27-1. 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).*

The Kinections project is being run in collaboration with East Ayrshire Health and Social Care Partnership; the invitation was extended at the beginning of the project to all care homes in East Ayrshire (n=19) to participate in this study. These care homes have been divided into four cohorts, with 4-5 care homes in each cohort.

The component of the study for which ethical approval is being sought from Scotland A REC committee will involve one care home. The care home is recognised as having particular expertise in supporting residents with advanced dementia and has agreed to be involved in this study as the care home manager is eager to share their experience with others.

The care home will continue to be advised that they have the option to opt-out at any time.

It is proposed that up to fifteen residents with a diagnosis of dementia, who do not have the capacity to give consent, will participate in research.

Those residents recruited will have had established lack of capacity with the relevant Adults with Incapacity (Scotland) Act paperwork, for example, Section 47 certification, in place.

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:

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

○ Yes ◉ No

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

Letter to be sent by care home manager/nominated person to welfare guardian/relative informing them of the study and requesting they get in touch if they would like to hear more/consent for the resident to become involved.

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.

If/when welfare guardian/relative responds they are invited to have a conversation with the researcher for further description and discussion about the study and their perceptions of whether the resident, has expressed in the past, or to the best of their knowledge, that they would like to be involved. They are also offered a copy of the Information Sheet and Consent Form.
Following written consent being obtained in line with the Adults with Incapacity (Scotland) Act, further principles as outlined by Alzheimer Scotland (2000) will also be followed. These are:
(i) Whatever the degree of dementia, the person with dementia should be made aware, as far as possible, of what will be involved.
(ii) if the person with dementia is not willing to participate, then he or she should not be recruited to the research project (even if it is a relative's wish that they participate).

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?

The welfare guardian/ relative will have up to one week to decide whether or not they are agreeable to the person being involved in the study.

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)*

All necessary measures will be taken, such as the hiring of interpreters including BSL interpreters if necessary.

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:

While written informed consent will not be sought from the participants, but from their next of kin/welfare guardian, the researcher will use process consent when engaging with participants, and collaborate with care home staff to establish how the participant may express assent/ dissent. This will include introducing herself, giving some detail as to what she will be doing, and asking their permission to sit alongside them, or engage in the activity in which the participant is engaged.

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
- [x] 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:
Regarding publication of data that might allow identification of individuals.
The site in which this study is taking place is sharing publicly, for example through social media, their involvement in the study. However, all measures will be taking when sharing case examples from the care home that identifiable features are completely removed or adequately anonymised.

If the data also refers to a member of staff/ relative/ visitor their consent will also be sought prior to sharing the data.

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.*

The default position will be for all data to be pseudo-anonymized.

As the care home may themselves decide to talk about their involvement in the study, the researcher will ensure that any potentially distinguishing features of the person with a dementia, that would result in them being identifiable, are not included in the field notes that are generated.

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.*

Personal data will be not be collected as part of this study.

The data collected will refer to the interaction between the resident and the staff member/visitor.

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

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

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

A49-1. 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.
No known suitable register for this type of study.

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 A5-1.

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

☑ Peer reviewed scientific journals
☑ Internal report
☑ Conference presentation
☑ 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)

The pseudo-anonymised findings and subsequent learning in the project will be disseminated across the care homes participating in the project.
Further dissemination networks include publication in peer-reviewed journals, presentation at conferences and other learning events, publications through the Life Changes Trust network and the My Home Life network.

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.
Informal feedback will be given in the moment such as, 'thank you for telling me about that/letting me join you today it's important because.....'.

While the participants who lack capacity may not be actively involved in the formal processes for the dissemination of the findings, it is hoped that through the ongoing feedback with staff that the participants may benefit from the emerging findings.

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:
Standard practice for gaining ethical approval in the University of the West of Scotland has been adhered to.
The original ethical approval for Phase 1 of the study was approved by the then School of Health, Nursing and Midwifery Ethics Committee in Feb 2018
A further submission for amendments was made in June 2018- correspondence included in this application

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: 15
Total international sample size (including UK):
Total in European Economic Area:

Further details:
Maximum of 15 residents from one care home.

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 of a maximum of 15 residents what is considered to be a feasible number of observation events for one researcher to carry out in the given timeframe (over the maximum of 3 months in which they will be carrying out research in the home).
Whilst the aim of this sample size is not to suggest the findings are generalizable, it is hoped that within this number that there will be a diversity in terms of ways of self-expression, interests and preferences.

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 data generated will be reviewed for evidence of interactions/activities/moments which appeared to be positive for the person with a dementia. An example of this might be where staff are engaging with the participant to find out what the person would like for their time in the social space, and how the participant responds to these engagements.
The data (field notes) will be examined for information of what might have helped this to be a positive experience.
The data will be shared with staff in the care home, to deepen understanding and learning about supporting relationships and building community.
The data will then be shared with members of the Project Team for further review, and co-analysis.

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.*

	Title	Forename/Initials	Surname
	Dr	Edel	Roddy
Post	Research Fellow/ Kinections Project Lead		
Qualifications	PhD, B Sc (Nursing)		
Employer	UWS		
Work Address	Stephenson Place		
Post Code	G720LH		
Telephone	01698283100		
Fax			
Mobile			
Work Email	edel.roddy@uws.ac.uk		

	Title	Forename/Initials	Surname
	Dr	Alison	McLaughlin
Post	Research Assistant		
Qualifications	Prof Doc (Counselling Psychologist)		
Employer	University of the West of Scoltand		
Work Address	Stephenson Place		
Post Code	G720LH		
Telephone	01698283100		
Fax			

Mobile	
Work Email	alison.mclaughlin@uws.ac.uk

Title	Forename/Initials	Surname
Dr	Annette	Coburn

Post	Lecturer- Community Education
Qualifications	PhD
Employer	University of the West of Scotland
Work Address	Stephenson Place
Post Code	G720LH
Telephone	01698283100
Fax	
Mobile	
Work Email	annette.coburn@uws.ac.uk

Title	Forename/Initials	Surname
Mr	Charlie	Allan

Post	Service Officer (Care Homes for Older People)
Qualifications	
Employer	East Ayrshire Health and Social Care Partnership
Work Address	9 Balmoral Road Kilmarnock
Post Code	KA31HL
Telephone	01563 503340
Fax	
Mobile	
Work Email	val.allen@east-ayrshire.gov.uk

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

Commercial status: Non-Commercial

If Other, please specify:

Contact person

Name of organisation	University of the West of Scotland
Given name	W.Gordon
Family name	Mackay
Address	Lanarkshire Campus, Stephenson Place
Town/city	Blantyre
Post code	G720LH
Country	United Kingdom
Telephone	01698283100
Fax	
E-mail	w.mackay@uws.ac.uk

A65. Has external funding for the research been secured?

Please tick at least one check box.

- [x] 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:

Please give details of funding applications.

Organisation	Life Changes Trust
Address	Edward House 199 Sauchiehall Street Glasgow
Post Code	G2 3EX
Telephone	01412129600
Fax	
Mobile	
Email	colm.mcbriarty@lifechangestrust.org.uk

Funding Application Status: (•) Secured ( ) In progress

Amount: £245,000

Duration

Years: 3

Months: 0

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?

Dementia Programmes
Dementia-Friendly Communities

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.

A69-1. How long do you expect the study to last in the UK?

Planned start date: 02/03/2020

Planned end date: 01/06/2020

Total duration:

Years: 0 Months: 3 Days: 0

A71-2. 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 1

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
- ☐ 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 (eg community mental health teams)	
☐ Local authorities	
☐ Phase 1 trial units	
☐ Prison establishments	
☐ Probation areas	
☑ Independent (private or voluntary sector) organisations	1
☐ 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.

☐ NHS indemnity scheme will apply (NHS sponsors only)

☑ Other insurance or indemnity arrangements will apply (give details below)

University of the West of Scotland Indemnity Insurance

Please enclose a copy of relevant documents.

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.

☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☑ Other insurance or indemnity arrangements will apply (give details below)

University of the West of Scotland Indemnity Insurance

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.

☐ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☑ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

University of the West of Scotland Indemnity Insurance

Please enclose a copy of relevant documents.

B. All research other than CTIMPs

In this sub-section, an adult means a person aged 16 or over.

B1. What impairing condition(s) will the participants have?

The study must be connected to this condition or its treatment.

Any form of advanced dementia including Alzheimer's disease, vascular dementia or Lewy Body dementia.

B2. Justify the inclusion of adults unable to consent for themselves. It should be clear why the research could not be carried out as effectively if confined to adults capable of giving consent.

The justifications of the inclusion of adults who are unable to consent are outlined next.
To develop a deeper understanding of the lived experience which has been subject to limited exploration.
To enact a basic shift in power inequalities, to challenge the assumption that people who lack capacity are unable to share their views and experiences.
To ensure that efforts are made for the most marginalised of voices of experience to be represented in their communities.

There is now a recognition that research into the experiences of people with dementia should move away from the biomedical model and that ethically sound research with people with dementia is possible, including into the later stages of the illness (Norman, 2006; Cowdell, 2008; Scottish Dementia Working Group Research Sub-group, 2014). The majority of studies which include people with dementia focus on the earlier stages of the illness (Cowdell 2008). This study will gain an understanding of the experience of people with dementia as members of the care home community, including those in the later stages of the disease and who lack capacity.

Previous studies of experiences of people with mild to moderate dementia in general hospitals have illuminated subtle yet devastating experiences of people with dementia. Digby et al. (2012) and Cowdell (2010) discovered how distressing and hostile 'out of sight' conversations were perceived to be by people with dementia. A sense of loneliness, powerless and alienation was all reported by people with dementia in the study by Digby et al. (2012). The intention of including people with dementia who lack capacity in this study is to ensure that their lived experiences are examined to discover how they experience their community in a care home.

It is known that people with advanced dementia are excluded from research studies when classed as vulnerable and unable to give informed consent to participate in research. While this approach provides appropriate protection for the vulnerable adult, these protections also result in limited research into health, wellbeing and quality of life for this growing population of people. Research into the experience of advanced dementia in care homes is required to inform current and future knowledge, care, living conditions and treatment to support the highest quality of life possible.

B3. Who in the research team will decide whether or not the participants have the capacity to give consent? What training/experience will they have to enable them to reach this decision?

No member of the research team will assess capacity.

The potential research participants will have been assessed as lacking the capacity under the AWI (Scotland) Act and therefore has Welfare guardian in place. This will be confirmed through liaison with the Care Home Manager and their next of kin/Welfare Proxy decision maker.

B4. Does the research have the potential to benefit participants who are unable to consent for themselves?

(●) Yes ( ) No

If Yes, please indicate the nature of this benefit. You may refer back to your answer to Question A24.

People with dementia participating in research have reported a sense of reciprocal achievement; this includes feelings of experiencing their self and experiences being acknowledged as valued and valuable Van Baalen et al. (2010).
For the specific people with dementia in this project, the benefit results from being able to contribute to a community which has valued their in the moment experiences and through the study will take action to emphasise wellbeing, inclusion, joy and enjoyment. As this project design is dynamic and responsive to the research findings, there is the potential for the participant to benefit as a direct result of knowledge gained during the observation.

In instances where the observation is stopped due to the participant becoming stressed or distressed for any reason, the researcher will where possible use this opportunity to speak with staff about the support of people with dementia during times of stress and distress.

B5. Will the research contribute to knowledge of the causes or the treatment or care of persons with the same impairing condition (or a similar condition)?

◉ Yes ○ No

If Yes, please explain how the research will achieve this:

The pseudo-anonymised findings and subsequent actions in the project will be disseminated across the care homes participating in the wider Kinections project.
Further dissemination networks include publications for example in peer-reviewed journals, publications through the Life Changes Trust network and the My Home Life network.

B6. Will the research involve any foreseeable risk or burden for these participants, or interfere in any way with their freedom of action or privacy?

○ Yes ◉ No

Question B7-1 applies to any participants recruited in Scotland.

B7-1. What arrangements will be made to identify and seek consent from a guardian or welfare attorney or, if there is no such person, from the participant's nearest relative?

A letter will be sent by care home manager to the next of kin/Welfare guardian informing them of the study and requesting they get in touch if they would like to hear more and discuss consent for the resident to become involved.

Please enclose a copy of the written information to be provided and the consent form to be used. The information sheet should provide information about the research similar to that which might be given to participants able to consent for themselves.

B9. What arrangements will be made to continue to consult such persons during the course of the research where necessary?

As the researcher is at the research site frequently- up to twice monthly, next of kin/Welfare guardian will have the opportunity to speak with the researcher via prior arrangement. The researcher will seek the person's consent to access their preferred contact details from the care home staff, should they need to be contacted during the course of the research.

B10. What steps will you take, if appropriate, to provide participants who are unable to consent for themselves with information about the research, and to consider their wishes and feelings?

As the researcher will participating in usual activities as a social observer, it is observation which is new for the participants. Ongoing information will be provided in a conversational form. Telling the participant what is happening and asking if it is alright for the researcher to be there.

B11. Is it possible that the capacity of participants could fluctuate during the research? How would this be handled?

It is unlikely that the participants will regain capacity during the research study as we will not select participants who are acutely unwell or who have an unpredictable, variable dementia presentation.

B12-1. What will be the criteria for withdrawal of participants?

Withdrawal of the participants (who cannot consent) from the social observations will take place if:
During the study, they no longer spend time in social spaces in the care home
There are two episodes of signs of dissent or distress at the researcher presence are observed. The researcher will

speak with care home staff/ next of kin/ welfare guardian about the participants' usual pattern of behaviour regarding dissent, and other factors which may have led to the person to experience distress. If the care home staff/ next of kin/ welfare guardian think that the distress may have been dissent to the researcher's presence, then the participant will be withdrawn from the study.

Examples of dissent include:
Verbal cues and utterances: no, go away, why are you here?
Non-verbal gestures and any other behaviour or emotional signals; walking off, grimacing, eye closing, turning away from the researcher.

B13. Describe what steps will be taken to ensure that nothing is done to which participants appear to object (unless it is to protect them from harm or minimise pain or discomfort).

As the researcher will be participating in usual activities as a social observer, it is observation which is new for the participants. The observation is for episodes of 15 minutes, blended into the participant's usual daily routines and events.
The criteria for withdrawal of participants is stringent and will be followed. This will include the researcher observing for signs of dissent or discomfort at being observed and stopping the observation immediately if those described signs are displayed by the participant.

B14. Describe what steps will be taken to ensure that nothing is done which is contrary to any advance decision or statement by the participant?

All advanced decisions and statements will be explored by with the next of kin/Welfare guardian. The next of kin/Welfare guardian will also be asked by the researcher if they are aware of the potential participants previous views on research participation; and if these were suggestive of a preference not to be involved in social research.

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 further information please refer to guidance.*

Research site		Investigator/ Collaborator/ Contact	
Institution name	Crossgate Care Home	Title	Care Home Manager
Department name		First name/ Initials	Heather
Street address	Meikelwood Road	Surname	Taylor
Town/city	Kilmarnock		
Post Code	KA3 2EL		

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 fulfil the responsibilities of the chief investigator for this study as set out in the UK Policy Framework for Health and Social Care Research.

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

4. 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.

5. 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.

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

7. 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.

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

9. 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 2018.

10. 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.

11. 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 2018.

12. 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 Health Research Authority (HRA) together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after the issue of the ethics committee's final opinion or the withdrawal of the application.

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

HRA 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
- ( ) Sponsor
- ( ) Study co-ordinator
- ( ) Student
- ( ) Other – please give details
- ( ) None

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.

Signature: .....

Print Name: Anna Jack-Waugh

Date: 20/09/2019 *(dd/mm/yyyy)*

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.

   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.*

6. 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.

7. 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 publically 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 Dr William Mackay on 17/01/2020 10:53.

Job Title/Post:	Senior Lecturer
Organisation:	University of the West of Scotland
Email:	w.mackay@uws.ac.uk