

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 enter a short title for this project (maximum 70 characters)

C:EVOLVE Virtual world for counselling young people affected by cancer

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. Will the study involve the use of any medical device without a CE Mark, or a CE marked device which has been modified or will be used outside its intended purposes?

☐ Yes ☒ No

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

- a) Does the study involve the use of any ionising radiation? ☐ Yes ☒ No
- b) Will you be taking new human tissue samples (or other human biological samples)? ☐ Yes ☒ No
- c) Will you be using existing human tissue samples (or other human biological samples)? ☐ Yes ☒ No

3. In which countries of the UK will the research sites be located?(Tick all that apply)

☐ England

- ☐ Scotland
☒ 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 review bodies are you applying to?

- ☒ NHS/HSC Research and Development offices
☐ Social Care Research Ethics Committee
☒ Research Ethics Committee
☐ National Information Governance Board for Health and Social Care (NIGB)
☐ National Offender Management Service (NOMS) (Prisons & Probation)

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

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

- ☐ Yes ☒ No

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 NIGB Ethics and Confidentiality Committee 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

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

☐ Yes ☒ No

DRAFT

Integrated Research Application System

Application Form for Other research

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

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

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
C:EVOLVE Virtual world for counselling young people affected by cancer

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

The C:EVOLVE Project: A feasibility study of the development and evaluation of an online virtual environment for counselling young people affected by cancer.

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Dr	Ceri	Phelps
Post	Senior Lecturer		
Qualifications	BA(Hons), MPhil, PhD, CPsychol, HPC registered Health Psychologist, AFBPsS		
Employer	Centre for Psychology & Counselling		
Work Address	Swansea Metropolitan University		
	Townhill Campus		
	Townhill		
Post Code	SA2 OUT		
Work E-mail	ceri.phelps@smu.ac.uk		
* Personal E-mail	ceri.phelps@smu.ac.uk		
Work Telephone	01792 482084		
* Personal Telephone/Mobile	07977051203		
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 R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Dr	Ceri	Phelps
Address	Swansea Metropolitan University		

Townhill Campus
 Townhill
 Post Code SA2 OUT
 E-mail ceri.phelps@smu.ac.uk
 Telephone 01792 482084
 Fax

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

Applicant's/organisation's own reference number, e.g. R & D (if available):

Sponsor's/protocol number:

Protocol Version:

Version 1

Protocol Date:

29/03/2013

Funder's reference number:

Project website:

Registry reference number(s):

The Department of Health's Research Governance Framework for Health and Social Care and the research governance frameworks for Wales, Scotland and Northern Ireland set out the requirement for registration of trials. Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for publication only if it has been registered in an appropriate registry. Please see guidance for more information.

International Standard Randomised Controlled Trial Number (ISRCTN):

ClinicalTrials.gov Identifier (NCT number):

Additional reference number(s):

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

☐ Yes ☒ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of 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 website of the National Research Ethics Service following the ethical review.

Tenovus the Cancer Charity have recognised a need to offer an alternative form of counselling for young people in Wales who have been affected by cancer in their lives and who do not make use of traditional face-to-face counselling. In line with advances in online therapy whereby individuals can seek and receive psychological support by a trained professional over the Internet rather than face-to-face, Avatar-based therapy is starting to be explored within the field of counselling and psychotherapy. The aim of this research project is to identify the feasibility and acceptance of a "virtual reality counselling world" amongst young people affected by cancer in Wales. This virtual counselling world will enable young people to design their own personal avatar and to engage in a therapeutic session (through text, images and/or speech) via these avatars. Young people affected by cancer in their lives will be involved in all stages of the

project through a Project Steering Group. The design of the virtual counselling world will be greatly influenced by the ongoing input/feedback provided by a "young persons' volunteer panel" which will include young people aged between 13 and 25. This protocol/application relates to the first phase of this study, which involves the recruitment of volunteers to the young person's panel, contribution to a closed project Facebook page, and initial development of the virtual reality world. The second phase of this study which represents the live pilot evaluation phase will seek NHS ethical approval within the next few months.

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.

We have identified a number of ethical considerations regarding i) engaging young people in research and ii) creating and use of a face book page by the young people. Following are the main ethical considerations about each issue and how they will be addressed:

i) When engaging young people in research the researcher/s will take into account:

Competence or vulnerability

a) The young people's competencies, perceptions and frameworks of reference, which are different to those of adults. The researcher/s will ensure that children are freely given fully informed consent and the right to withdraw from research participation.

b) The children's potential vulnerability to exploitation in interaction with adults, and adults' specific responsibilities towards children. The researcher/s will ensure that children's autonomy will be regarded and their voices will be adequately represented in the research.

Consent

a) The researcher/s will ensure that a fully informed consent is sought from the young person. When parental consent is required the researcher will use opt-in consent to avoid any misunderstanding and to make sure that the parents and the children fully understand that the participation is voluntarily.

Providing information

a) To avoid any misunderstanding and/or confusion, the researcher/s will provide clear and accessible information, specially designed for children in an age-appropriate way.

Confidentiality and disclosures

a) All the information provided by the young people engaged in the research will be dealt with in confidence. However according to the guidelines of the Department of Health's Research Governance Framework (2010), if there are any concerns that the young people may be at risk, their information will be disclosed to the relevant professional, e.g. GP for child protection purposes.

Dissemination and feedback

a) The findings of this research project will be disseminated among the relevant health professionals i.e. Tenovus and possibly other cancer research and research organisations as part of the university's policy for wider dissemination. Young persons will be given sufficient space to decide if they would like to take part in dissemination activities and in what ways, e.g. attending a seminar to present the data.

b) The researcher/s will report the findings back to children and young people who take part in research.

ii) The use of face book page and online date

Privacy

a) To maximise the online privacy of our young persons' personal details and the contents of the facebook page, the researcher/s will endeavour to protect the privacy of the contents. All names and personal details will be anonymised unless otherwise agreed with the young persons. Participants should be identifiable and contactable by the researchers should a concern arises.

Security

In order to secure the online activities by the young persons all participants will be asked to:

1. Create a strong, unique password which contain letters, numbers and symbols as opposed to just letters.
2. Log out each time they are away from the computer.
3. Never share their password or annotate it where someone may find it.
4. Ensure that they are operating on a secure browser.
5. Report any evidence of hacking as soon as possible

Safety

To ensure the safety of the contents of the face book page i.e. posts, conversations, photos, the researcher/s will monitor to verify the safety of the contents on a daily basis.

Data protection

All personal information provided by the young persons will be kept confidential. However personal information can be processed, if consent has been sought , Data protection legislation (Data Protection Act, 1998)

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

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

Further comments (optional):

Note: This question only applies to the REC application.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. Please tick all that apply:

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

Phase I of the study does not involve any research evaluation other than the possible use of comments/photographs posted on the closed Facebook page in the phase I report/associated publications.

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

The principle research objective of the overall project is to explore the therapeutic value and acceptance of an interactive, avatar-based online counselling programme for young people (12-25) affected by cancer.

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

a lay person.

n/a

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

The adverse psychological impact of cancer is recognised worldwide and the high prevalence of disorders such as anxiety and depression among people affected by cancer has been well-documented (Li, et al. 2013; Tulskey et al. 2011). Recent advances in cancer treatment have resulted in an increase in survival rates for cancer (Li et al., 2010a). However cancer and its treatments can not only adversely affect the physical well-being of the cancer survivors, but their psychosocial well-being as well (Langeveld et al., 2004). Radiotherapy, chemotherapy and surgical intervention could have long-term effects on the psychosocial wellbeing of survivors, which include increased depression and decreased self-esteem (Essen et al., 2000; Stam et al., 2006; Zeltzer et al., 2009). Further, the impact of cancer on cancer patients' families and carers are of significant importance. Cancer patient's families and carers may adjust to the situation, but can experience high levels of emotional distress or psychiatric morbidity (major depressive illness, anxiety or adjustment disorders) (Pitceathly and Maguire, 2003). Large numbers of people are now choosing to access internet counselling online which has grown significantly in the last decade (Barak, et al. 2008; Chester and Glass 2006). Interactive online counselling provides a unique opportunity for people to access counselling services without the historical constraints of time and logistics. Online counselling can offer the user a perception of a sense of privacy and anonymity that cannot be accessed by traditional counselling (Maheu & Gordon, 2000). Young people have been shown to be drawn to this method of therapy as they have grown up with computers and may conduct many relationships through them. Research suggests that effective therapeutic relationships can be formed with young people online (King, et al. 2006; Hanley 2012) and that it is a service which is valued and used by young people (Beattie, et al. 2006). We are not aware of any other cancer charity in the UK who have already developed an online counselling service in the manner intended within this project, with most charities/support groups (including those aimed specifically at younger people) offering online support groups/forums/digital stories as distinct from delivering online counselling. Whilst most forms of online counselling for people with cancer still involve simple email exchanges (David, Schlenker, Prudlo & Larbig, 2011), the use of avatars as a mechanism through which to achieve psychological benefit is starting to be explored in other counselling settings (e.g., Beattie et al., 2006; <http://www.Kooth.com>). It is recognised that children who have suffered from cancer often miss out on schooling and may be disadvantaged in later years in employment (Larcombe et al, 1990; Pang et al., 2008). The engagement with avatars is recognised as being familiar to most young people who are used to engaging with virtual reality computer games. Younger age groups affected by cancer have been found to have higher levels of internet use (Eysenbach, 2003) and have been found to report positive experiences from engaging with online counselling (Hanley 2012; King, et al. 2006).

Although there is an increasing body of research literature supporting the development of online counselling (e.g. Barak et al., 2008), only a few of studies have investigated the online therapeutic alliance with young people. The lack of evidence in the literature indicates the 'neglect' of the alliance in youth counselling in general (Green, 2006), but also reflects the newness of such provision. Therefore there is a need to determine the potential use of Avatar-Based counselling through a "virtual counselling world" among young people affected by cancer.

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.

This research project comprises of two phases, however this application relates to the phase 1 of the project.

Phase I

a) Setting up the "Young Persons' Volunteer Panel" and initial development of the "Virtual Counselling World"

A crucial element of this project is to engage young people with both the initial development and piloting of the virtual counselling world. A Young Persons' Volunteer Panel will be established which will consist of 6-8 young people between the ages of 13 and 25. The Young Persons' Volunteer Panel will meet monthly and will provide input into all design stages of the project and take part in the ongoing piloting of the virtual reality counselling world in the first six months of the project.

The young person's volunteer panel will consist of student volunteers aged 18-25 (n=4) from both the Psychology & Counselling undergraduate programmes and Applied Computing programmes (see Appendix C for internal advert) and young people aged 13-18 (n= 4-6) with some experience of, or awareness of, the impact of cancer on young people and their families. These young people will be recruited through existing links with schools in the Swansea area and/or existing Tenovus contacts providing they live within easy travelling distance of Swansea Metropolitan University.

All of the young people on the Volunteer Panel will have the opportunity to contribute to the ongoing evaluation of the virtual counselling world as it develops and share their experiences of being part of this project through a closed

project Facebook page. Two representatives from the Young Persons' Volunteer Panel will attend key project steering group meetings. The Volunteer Panel will also be used prior to the evaluation phase of the project in order to ensure that all evaluation and consent materials are comprehensible and easy to complete, and will track their experiences through an online closed Facebook page.

Phase II (to be submitted through a separate ethics application in due course)

Phase II will represent a "live" pilot study of the acceptability and psychological benefits of the "Virtual Counselling World" amongst young people affected by cancer in Wales.

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

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

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

Design of the research

Participants from the Young person's Volunteer Panel will be involved in the initial and ongoing development of the project. Their involvement will include sharing ideas, experiences and opinions about the development of the Avatar-based virtual counselling world and using the closed Facebook page to record these thoughts and processes.

Volunteers from the Young Person's Volunteer Panel will pilot the project by creating an Avatar for themselves and try on the virtual counselling world. They will then feed back to us about their experience which will further inform the development of the project prior to the Phase II live pilot evaluation.

Dissemination of findings

Participants from the Young Person's Volunteer Panel will also be given the opportunity to get involved in the dissemination of the Phase I findings through a creative display at the end of the project (the exact nature of this display/dissemination will depend upon the preferences of the group members, within ethical and good practice guidelines).

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- ☐ Blood
- ☐ Cancer
- ☐ Cardiovascular
- ☐ Congenital Disorders
- ☐ Dementias and Neurodegenerative Diseases
- ☐ Diabetes
- ☐ Ear
- ☐ Eye
- ☒ Generic Health Relevance
- ☐ Infection
- ☐ Inflammatory and Immune System

- ☐ Injuries and Accidents
☐ Mental Health
☐ Metabolic and Endocrine
☐ Musculoskeletal
☐ Neurological
☐ Oral and Gastrointestinal
☐ Paediatrics
☐ Renal and Urogenital
☐ Reproductive Health and Childbirth
☐ Respiratory
☐ Skin
☐ Stroke

Gender: Male and female participants

Lower age limit: 13 Years

Upper age limit: 25 Years

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

Young persons aged 13-25 who demonstrate an awareness of and sensitivity to the impact of cancer on young people and their families will be eligible for becoming a project volunteer. These individuals may not necessarily have personal experience with cancer.

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

Young people who express an interest but whom the research team feel are too vulnerable to take part in the research will not be allowed to join the volunteer panel.

Young people who express an interest but whom the research team feel do not have the maturity, sensitivity or awareness to make a meaningful contribution to the panel will not be allowed to join the panel.

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
Seeking consent	2			CI and the research assistant
Attendance at monthly volunteer group meeting over a six month period	6	2 hours		CI and the research assistant

A19. Give details of any clinical intervention(s) or procedure(s) to be received by participants as part of the research protocol. These include uses of medicinal products or devices, other medical treatments or assessments, mental health interventions, imaging investigations and taking samples of human biological material. Include procedures which might be received as routine clinical care outside of the research.

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
N/A				

A20. Will you withhold an intervention or procedure, which would normally be considered a part of routine care?

☐ Yes ☒ No

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

Participants from the Young Person's Volunteer Panel are expected to be in the research study for a period of 6 months.

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.

Swansea Metropolitan University's Child Protection Policy will be adhered to ensure the safety of the young volunteers whilst on-site during the monthly meetings, and all project team members and student volunteers over the age of 18 who will be interacting with the young person's volunteer panel will be CRB checked.

One potential risk to the participants can be the adverse affect of taking part in discussions related to cancer and its effects, as some of the young people may find occasional topics of conversation to be uncomfortable or upsetting. To minimise the potential risk at this stage of the project, we are taking a cautious approach and not specifically targeting young people directly affected by cancer, or who have experienced cancer within their families. However, we are expecting the volunteers to demonstrate a number of qualities in relation to the project and its contents, e.g. an understanding of the issues that may be faced by young people affected by cancer in some way in their lives, an interest in/experience of virtual worlds.

If a potential volunteer has had a recent personal experience of cancer in the family the Project Team will carefully consider whether the individual is too vulnerable to take part in the project. For those aged over 18 years, this will involve discussion with key members of the project team including experienced qualified BACP accredited counsellors and a cancer genetic counsellor and appropriate informed consent. For those aged under 18, this will involve detailed conversations between members of the project team and the young persons' guardian/parent and school teachers and appropriate informed consent at all levels.

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

If Yes, please give details of procedures in place to deal with these issues:

It is possible that some participants might find some of the topics discussed during the group meeting to be upsetting. For procedures in place please see question A22.

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

There will no direct clinical benefit to the volunteers in taking part in this project.

The young people who take part in the project and contribute towards the design and the development of the project will be co-producers of rich data that will capture their thoughts about the future delivery of online counselling services. Participants will enhance their knowledge about cancer, counselling and virtual counselling world by taking part in group discussions. Further, they will improve their person, people and communication skills as well as IT skills. Taking part in this project will provide a unique opportunity for the young people and the student volunteers to voice their opinion and gain experience through involvement in a research project.

A25. What arrangements are being made for continued provision of the intervention for participants, if appropriate, once the research has finished? May apply to any clinical intervention, including a drug, medical device, mental health intervention, complementary therapy, physiotherapy, dietary manipulation, lifestyle change, etc.

N/A

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

The potential risks for the researchers in this phase of the project relate to the potential behaviour of project volunteers during the monthly meetings. Whilst the rigorous recruitment process should minimise the likelihood of young people with significant behavioural problems being involved in the project, there is still a possibility that aggressive behaviour could occur. The project team will ensure that there is a minimum of two project team members present at each group meeting and have also enlisted the support for SMU's Community Engagement Officer to help facilitate these groups.

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 social care or GP records, or review of medical records. Indicate whether this will be done by the direct care team or by researchers acting under arrangements with the responsible care organisation(s).

MAS - NEED TO STATE HERE THE FOLLOWING :

STUDENTS - APPROACHED BY EMAIL TO ALL PSYCH/COUNSELLING STUDENTS - IF INTERESTED THEY WERE ASKED TO CONTACT CI

SCHOOLS - IDENTIFIED BY HEAD/SCHOOL CONTACT IN FIRST INSTANCE

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

☐ Yes ☒ No

Please give details below:

No personal information will be available to the project team prior to potential participants expressing interest in becoming a volunteer.

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

☒ Yes ☐ No

If Yes, please give details of how and where publicity will be conducted, and enclose copy of all advertising material (with version numbers and dates).

EMAIL WITH INFO ABOUT STUDY TO STUDENTS....

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

As in A27,

STUDENTS - APPROACHED BY EMAIL TO ALL PSYCH/COUNSELLING STUDENTS - IF INTERESTED THEY WERE ASKED TO CONTACT CI

SCHOOLS - letters distributed BY HEAD/SCHOOL CONTACT IN FIRST INSTANCE

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.

MAS- PASTE CONSENT PROCESS FROM PROTOCOL HERE

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 recruitment and consent process will ensure that those who agree to consent to becoming a volunteer have had multiple opportunities over the course of several weeks to have fully considered involvement in the project and to raise any questions or concerns about involvement in the project.

A32. Will you recruit any participants who are involved in current research or have recently been involved in any research prior to recruitment?

☐ Yes
☐ No
☐ Not Known

If Yes, please give details and justify their inclusion. If Not Known, what steps will you take to find out?

n/a although one consideration of the project will be to ensure that commitment to the project will not impact detrimentally upon other academic commitments.

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)**A33-2. What arrangements will you make to comply with the principles of the Welsh Language Act in the provision of information to participants in Wales?**

Within the context of this pilot study it will not be possible to conduct the group meetings through the medium of Welsh and therefore it is not considered appropriate to send out recruitment materials in Welsh.

A34. What arrangements will you make to ensure participants receive any information that becomes available during the course of the research that may be relevant to their continued participation?

Volunteers will be informed immediately of any essential information via their email addresses and the closed project facebook page.

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:

CONFIDENTIALITY

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

Storage and use of personal data during the study**A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? (Tick as appropriate)**

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

Further details:

A37. Please describe the physical security arrangements for storage of personal data during the study?

Names, contact details and addresses for volunteers will be stored securely in a locked filing cabinet in the CI's office.

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 names, contact details and addresses for volunteers will be stored for up to one year following the publication of any results from the study. It is not considered necessary to retain this data for a longer period of time.

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.

Only the CI and Research Assistant will have access to volunteers' contact details.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

The data generated by this phase of the study only relates to the potential use of comments and photographs placed on Facebook. Analysis of this data will take place on University premises by the CI and RA only.

A42. Who will have control of and act as the custodian for the data generated by the study?

	Title	Forename/Initials	Surname
	Dr	Ceri	Phelps
Post	Senior Lecturer		
Qualifications	BA(Hons), MPhil, PhD, CPsychol, HPC registered Health Psychologist, AFBPsS		
Work Address	Swansea Metropolitan University		
	Townhill Campus		
	Townhill		
Post Code	SA2 OUT		
Work Email	ceri.phelps@smu.ac.uk		
Work Telephone	01792 482084		
Fax			

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

A44. For how long will you store research data generated by the study?

Years: 5

Months:

A45. Please give details of the long term arrangements for storage of research data after the study has ended. Say where data will be stored, who will have access and the arrangements to ensure security.

INCENTIVES AND PAYMENTS

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

☒ Yes ☐ No

If Yes, please give details. For monetary payments, indicate how much and on what basis this has been determined. Volunteers will receive a £100 Amazon voucher upon completion of the study.

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

A50-1. Will the research be registered on a public database?

The Department of Health's Research Governance Framework for Health and Social Care and the research governance frameworks for Wales, Scotland and Northern Ireland set out the requirement for registration of trials. Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for publication only if it has been registered in an appropriate registry. Please see guidance for more information.

☐ Yes ☒ No

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

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)

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

The content of the Facebook postings will be analysed using a basic thematic analysis to explore the emerging themes and issues. All data will be anonymised with the use of pseudonyms in place of actual names and any other identifiable information removed or changed to protect anonymity.

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.

All participants will receive a lay summary of the Phase I study report and have the option of requesting a summary at the end of Phase II also.

5. Scientific and Statistical Review

A54-1. 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:

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.

A56. How have the statistical aspects of the research been reviewed? Tick as appropriate:

- ☐ Review by independent statistician commissioned by funder or sponsor
- ☐ Other review by independent statistician
- ☐ Review by company statistician
- ☐ Review by a statistician within the Chief Investigator's institution

- ☐ Review by a statistician within the research team or multi-centre group
- ☐ Review by educational supervisor
- ☐ Other review by individual with relevant statistical expertise
- ☒ No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

Title Forename/Initials Surname

Department

Institution

Work Address

Post Code

Telephone

Fax

Mobile

E-mail

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

n/a

A58. What are the secondary outcome measures? (if any)

n/a

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:

Total international sample size (including UK):

Total in European Economic Area:

Further details:

n/a

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.*

n/a

A61-1. Will participants be allocated to groups at random?

☐ Yes ☒ No

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.

Extent of use and engagement with the ecogarden will be explored. Preferences for use of the website versus the diary will be evaluated and the degree of use of both will be explored descriptively.

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

Post

Qualifications

Employer

Work Address

Post Code

Telephone

Fax

Mobile

Work Email

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status: ☐ NHS or HSC care organisation Commercial status:

☒ Academic

☐ Pharmaceutical industry

☐ Medical device industry

☐ Other

If Other, please specify:

Contact person

Name of organisation

Given name

Family name

Address

Town/city

Post code

Country
Telephone
Fax
E-mail

Is the sponsor based outside the UK?

☐ Yes ☐ No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A65. Has external funding for the research been secured?

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

What type of research project is this?

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

Other – please state:

Please give details of funding applications.

Organisation Tenovus the Cancer Charity
Address

Post Code
Telephone
Fax
Mobile
Email

Funding Application Status: ☐ Secured ☐ In progress

Amount:

Duration
Years:
Months:

If applicable, please specify the programme/ funding stream:

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

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? Please give details of subcontractors if applicable.

☐ Yes ☒ No

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: 20/05/2013

Planned end date: 20/05/2014

Total duration:

Years: 1 Months: 0 Days: 0

A71-1. Is this study?

☒ Single centre
☐ Multicentre

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

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
- ☒ Educational establishments 1
- ☐ Independent research units
- ☐ Other (give details)

Total UK sites in study: 1

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

☒ Yes ☐ No

A73-2. If yes, will any of these organisations be NHS organisations?

☐ Yes ☒ No

If yes, details should be given in Part C.

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

A project steering group will monitor the conduct of the research

A75-1. What arrangements will be made to review interim safety and efficacy data from the trial? Will a formal data monitoring committee or equivalent body be convened?

n/a

If a formal DMC is to be convened, please forward details of the membership and standard operating procedures to the Research Ethics Committee when available. The REC should also be notified of DMC recommendations and receive summary reports of interim analyses.

A75-2. What are the criteria for electively stopping the trial or other research prematurely?

Whilst the steps that have been in place for this phase of the study should make it unlikely that any unplanned for serious adverse consequences should occur, in the event of the members of the project steering group becoming concerned that participation in this phase of the project may be having unintended serious adverse effects on the participants then the decision will be made to immediately stop this phase of the study and an emergency Project Steering Group convened.

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)

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)

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)

Please enclose a copy of relevant documents.

A77. Has the sponsor(s) made arrangements for payment of compensation in the event of harm to the research participants where no legal liability arises?

- ☐ Yes ☒ No

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

- ☒ Yes ☐ No ☐ Not sure

PART B: Section 7 - Children

1. Please specify the potential age range of children under 16 who will be included and give reasons for carrying out the research in this age group.

2. Indicate whether any children under 16 will be recruited as controls and give further details.

3-2. Please describe the arrangements for seeking informed consent from a person with parental responsibility and/or from children able to give consent for themselves.

4. If you intend to provide children under 16 with information about the research and seek their consent or agreement, please outline how this process will vary according to their age and level of understanding.

Copies of written information sheet(s) for parents and children, consent/assent form(s) and any other explanatory material should be enclosed with the application.

PART C: Overview of research sites

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

Research site	Investigator/ Collaborator/ Contact
Institution name Swansea Metropolitan University	Title
Department name	First name/ Initials
Street address	Surname
Town/city	
Post Code	

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.
4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.
5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.
7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.
9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
 - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
 - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
 - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
 - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
 - May be sent by email to REC members.
10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.
11. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

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

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

- ☐ Chief Investigator
- ☐ 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:

Date: (dd/mm/yyyy)

DRAFT

D2. Declaration by the sponsor's representative

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

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.
2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.
3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.
4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
6. 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.

Signature:

Print Name:

Post:

Organisation:

Date: (dd/mm/yyyy)

DRAFT