

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)

The C:EVOLVE project: Online Counselling for young people (Phase II)

1. Is your project research?

☒ Yes ☐ No

2. Select one category from the list below:

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

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

☐ Other study

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

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

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

- ☐ England
- ☐ Scotland
- ☒ 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

Integrated Research Application System**Application Form for Research administering questionnaires/interviews for quantitative analysis or mixed methodology study****Application to NHS/HSC Research Ethics Committee**

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

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

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
The C:EVOLVE project: Online Counselling for young people (Phase II)

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

REC Name:

South West Wales Research Ethics Committee

REC Reference Number:

13/WA/0347

Submission date:

24/10/2013

PART A: Core study information**1. ADMINISTRATIVE DETAILS****A1. Full title of the research:**

The C:EVOLVE Project(Phase II): A pilot study of online counselling for young people affected by cancer.

A3-1. Chief Investigator:

	Title Forename/Initials Surname
	Dr Ceri Phelps
Post	Senior Lecturer in Psychology
Qualifications	CPsychol, AFBPsS, HPC Registered Health Psychologist
Employer	University of Wales Trinity St David, Swansea
Work Address	School of Psychology & Counselling
	Faculty of Social Sciences
	University of Wales Trinity St David, Swansea
Post Code	SA2 0UT
Work E-mail	ceri.phelps@sm.uwtsd.ac.uk
* Personal E-mail	ceri.phelps@sm.uwtsd.ac.uk
Work Telephone	01792 482084

* Personal Telephone/Mobile 07977051203

Fax 01792

** 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
	Prof Ann Edworthy
Address	University of Wales Trinity St David, Swansea Townhill Campus Swansea
Post Code	SA2 0UT
E-mail	ann.edworthy@sm.uwtsd.ac.uk
Telephone	01792482084
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: 21/10/2013

Funder's reference number: TIG2012-09

Project website:

Additional reference number(s):

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

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

☒ Yes ☐ No

Please give brief details and reference numbers.

Reference number- IRAS Project ID:130670

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

Phase I of this project started in May 2013 following NHS ethical approval, and involved the initial development of the online counselling world through an expert project steering group and a Young Persons' Panel. This current proposal is for the second phase of the project which represents a pilot feasibility study of the acceptability and effectiveness of the intervention.

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 (either personally affected or having cared for a family member with cancer) and who do not make use of traditional face-to-face counselling. The overall aim of this research project is to develop a virtual reality online counselling world and to explore the feasibility and acceptability of this intervention amongst young people affected by cancer in Wales. This online counselling world will enable young people to design their own personal avatar and to engage in an online counselling session via avatars. Phase I of this project involved the initial development of the online counselling world through an expert project steering group and a Young Persons' Panel. This current proposal is for the second phase of the project which represents a pilot feasibility study of the acceptability and effectiveness of the intervention. This phase will recruit young people between the ages of 13 and 25 who are either personally affected with cancer or who have had current or recent experience of having a family member with cancer. The study will explore uptake rates and retention for online counselling, the demographic profile of those who choose to take part in online counselling, and key therapeutic outcomes. If shown to be successful, the virtual reality counselling world may be adopted by Tenovus for ongoing delivery of cancer support services to young people throughout Wales, with huge scope for offering a wider alternative to face-to-face counselling for all age group and other counselling services.

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 project team recognise the clear ethical issues involved in this project, particularly with the potential age group involved (i.e., those under 18 years of age). Key ethical considerations at phase II of the study fall under two distinct areas: 1) issues related to the recruitment and participation of young people in this online research study and 2) issues related to the delivery of online counselling i.e., the intervention itself. Consideration of these issues has been paramount at each stage of the protocol development and are discussed further in relevant sections of this ethics form.

ISSUES RELATED TO THE RECRUITMENT AND PARTICIPATION OF YOUNG PEOPLE IN THIS ONLINE RESEARCH STUDY:

The respect for the autonomy and dignity of the young persons involved in this study is of paramount concern. Every effort has been made to respect the autonomy and dignity of our potential participants through the following mechanisms:

1) Readability of study information. The study advert, study information sheet and consent form have all been approved by the Young Person's Panel in Phase I for ease of comprehension and understanding. An adapted consent form has been created for participants under 18 years of age, and every effort has been made to ensure that Part 1 of the study information sheet in particular is easily understandable to young people, with younger participants being encouraged to discuss part 2 of the study information sheet with their parent or guardian to ensure that they understand it fully.

2) Valid informed consent and right to withdraw: This study has instigated a thorough informed consent process which includes 1) provision of a detailed but easily understandable written study information sheet which provides participants with all the information they need in order to understand what taking part in the study will mean for them and 2) a clear written informed consent process documenting that their decision to take part is voluntary and that they have a right to withdraw at any time.

3) Confidentiality of research data: The study information sheet makes it clear to all participants that they have a right to expect that information they provide when completing the research evaluations will be treated confidentially in line with the Data Protection Act (2004). It is made clear in the information sheet that only the pre-session CORE-YP and background demographics will be made available to the online counsellor (this is standard practice in many

counselling organisations) and that no other questionnaire data will be seen by the counsellor. The latter is an important consideration to ensure that study participants feel that they have complete honest evaluations of how the online sessions have made them feel. It is also made clear in the study information sheet that for research purposes, any data collected during the research study will be anonymised and will not be identifiable to any individual participant or person outside of the research team.

ISSUES RELATED TO THE DELIVERY OF ONLINE COUNSELLING I.E., THE INTERVENTION ITSELF

The British Association for Counselling and Psychotherapy (BACP) has proposed a number of ethical considerations in relation to the delivery of online counselling. In addition to the policies outlined above, the general BACP guidelines (2013) and the Welsh Assembly School-Based Counselling policies (2011) have been consulted in order to identify the following set of good practice guidelines for this study in terms of the delivery of online counselling and protection of young people within this virtual environment.

1) Safeguarding the child in an online counselling environment

It is important to identify that online counselling is appropriate for the presenting concern of the potential client. This will be achieved in the current study through undertaking an initial screening assessment to identify young people with more severe levels of distress. Individuals who exceed this cut-off score on the screening measure will be offered the opportunity to be referred into standard Tenovus counselling options (Skype, telephone or face-to-face counselling) or to another counselling organisation or clinical psychologist if deemed more appropriate by the Tenovus counselling service.

2) Electronic confidentiality and privacy issues during online counselling

Maintaining confidentiality and privacy is an important ethical issue in online counselling which will be addressed within the informed consent process. To maximise online security, the C:EVOLVE programme will use encryptions and firewalls that protect information from hackers or malware. The content of the sessions and any communication and materials will be password protected. The C:EVOLVE programme will also use the university's firewalls to protect against harmful viruses that can be received from or transmitted to others, including clients.

In relation to the confidentiality of the topics discussed during online counselling, it is made clear in the study information sheet that the content of the online counselling sessions themselves will not be made available to anyone in the research team and will not be published or analysed for any research purposes. The online sessions will be conducted through a secure server and encrypted password protected systems to ensure the online privacy and confidentiality of the counselling sessions. It will not be possible for the project team, counsellor or young person to access text from these online sessions once completed as the content will not be stored in this manner.

However, in line with appropriate policies, it is also made clear to study participants in the informed consent stage that absolute confidentiality of the content of the counselling sessions cannot be guaranteed, as the welfare of the young person will at all times take precedence over confidentiality. The information sheet includes the statement regarding the potential disclosure of information to a Designated Child Protection Person, if the counsellor has knowledge, concerns or suspicions that a child is suffering or is likely to be at risk of harm. Additionally, as is standard practice amongst practicing counsellors, it is indicated in the study information sheet that the counsellor may choose to discuss some aspects of the online counselling sessions with their own supervisor.

3) Minimising harm/distress during online counselling: It is important to acknowledge that in the context of the current study that the very nature of the problems that the participants present with during their online counselling sessions means that some level of psychological discomfort or distress is likely to be unavoidable. Indeed, the process of counselling often involves a "working through" of problems over time, and some increases in anxiety, worry or distress in the early stages of counselling are often a natural part of the therapeutic process. The procedure for minimising and monitoring potential harm during online counselling, will, wherever possible, mirror the robust procedures put in place in Tenovus for their face-to-face counselling sessions. The recruitment of a BACP-registered counsellor will ensure that the counsellor is comfortable and experienced with dealing with clients in crisis and is aware of appropriate response and referral options where necessary.

The capture of data relating to participants' psychological functioning and emotional changes over the course of the pilot study will enable the research team to monitor any evidence of the intervention making people highly distressed. Should any evidence of extreme distress be apparent that the counsellor feels unable to deal with due to the confines of online counselling, the individual will be referred through to the Tenovus counselling service in order to identify appropriate action and the project steering group will be convened to discuss the potential implications of this for the continuation of the study.

4) Right to pause or stop online counselling during online counselling

During the online counselling session itself, participants will be able to pause or exit the session at any time by pressing a simple button should they not wish to continue the session. Pressing the "pause" button will create an unreadable "blurred" version of the C:EVOLVE world to ensure confidentiality of the online session in the event that the session has been paused due to interruption or the need for the participant to leave the screen momentarily. The session can be restarted with a simple "continue session" button and re-entering their password.

If the participant does select the "exit" option at any time, a pop-up screen will appear reminding participants of how to make contact with the counsellor or research team if there are specific issues they wish to discuss, and reminding participants that the counsellor may decide to contact their emergency contact details if they are concerned about their welfare or that of others. They will also be provided with the contact number for further support and advice from Tenovus if they so choose at any point.

5) Maintaining Professional boundaries

All researchers working on the project who are also practitioners will seek to maintain their boundaries between the research role and practitioner role. Should members of the research team receive queries from potential or actual participants at any stage of the study, where it is appropriate for the research team to deal with queries this will be done within the team. However, should these queries seek specific psychological advice, support or specific information about cancer then these queries will be directed to Tenovus via the co-applicant Helen French. Our study will recruit an experienced, qualified counsellor who will adhere to ethical guidelines regarding multiple relationships between counsellor and client to avoid any potential harmful relationship.

6) Interruption of therapy due to technological problems

The potential of interrupting therapy due to technological problems is a concern in online counselling. In the event that a session is interrupted due to a power or connection problem, the counsellor will call the client. If the client does not receive a call within ten minutes of the disconnection or error, they can email or call the project team who will be on site at UWTSD at that time in order to liaise with the IT support function. If the connection is not restored they will be offered an alternative appointment and the opportunity to finish the session via telephone counselling or email. Information about what to do if an interruption happens and other technical issues will be given to participants through the Frequently Asked Question page provided prior to the first online session.

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)

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

The primary aim of Phase II is to obtain quantitative pilot data on the acceptability, likely usage, and therapeutic value of this online counselling world for young people affected by cancer

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

- 1) To evaluate the impact of the online counselling world on the therapeutic relationship from the counsellor's perspective using a reflective diary.
- 2) To provide recommendations regarding the potential pitfalls and challenges in relation to the future delivery of such online interventions.

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 (Tulsky et al. 2011). 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 and Gordon, 2000).

Young people have been shown to be particularly 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). Glueckauf and colleagues (2002) conducted a randomised controlled study to assess outcomes from online (video and audio) and face-to-face family counselling in 39 teenagers with epilepsy and their parents for six sessions. They found significant reductions in both problem severity and frequency in the treatment groups for up to six months post treatment. Another study by Day and Schneider (2002) compared process and outcome variables across three treatment groups: face-to-face, telephone and online (video) counselling. They found a statistically significant difference in the level of participation as clients in telephone and online counselling participated more actively than those in face-to-face group. Their findings suggested that the clients in the distance modes perhaps made more of an effort to communicate or took more responsibility for the interaction, or that perhaps the distance made those participants feel safer. Efstathiou (2009) used online counselling with both adults and teenagers for a broad variety of presenting concerns. Participants reported advantages of using online counselling such as: ease of use, speed, and anonymity, followed by uncertainty about traditional counselling. This study identified that the traditional social stigma toward seeking help and social factors hindering help-seeking behaviours (e.g., gender and physical appearance) appeared to be reduced when using online counselling.

Online interventions including therapist support and counselling have been delivered through a range of technologies and communication modes, both synchronously (in real-time) and asynchronously (Newman, et al., 2011). Studies of online therapy have addressed a broad range of mental health issues including panic disorder (Carlbring et al., 2006; Carlbring, Ekselius, & Andersson, 2003), insomnia (Strom, Pattersson, & Andersson, 2004), and smoking cessation (Strecher, Shiffman, & West, 2005) and have reported significant post treatment and follow up effects with such interventions (Kessler et al., 2009; Vernmark et al., 2010; Richards & Richardson, 2012).

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 et al. 2011), the use of avatars as a mechanism through which to achieve psychological benefit is starting to be explored in other therapeutic settings (Beattie et al., 2006; <http://www.Kooth.com>). 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).

The overall aims of this study therefore, funded by Tenovus the Cancer Charity, are 1) to develop an online virtual reality counselling world for young people affected by cancer, informed by young people, and 2) to evaluate the acceptability and potential effectiveness of this intervention with young people affected by cancer across Wales.

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 pilot evaluation in phase II will run for up to six months and will explore the uptake rates, retention, and impact of the intervention on key outcomes through inviting participants to engage in online counselling for up to six weekly sessions (mirroring standard practice at Tenovus).

Following recruitment and initial screening to ensure that eligibility criteria are met, young people will be able to access the virtual reality counselling world, create their own avatar, and engage in a weekly synchronous ("real-time") counselling session with a qualified counsellor. Key measures will be taken pre and post each counselling session, with additional measures taken at the final online counselling session to explore changes not only within sessions but also over time. The counsellor will also create their own avatar through which to conduct their counselling interactions and will track their experiences qualitatively through a reflective diary.

PARTICIPANTS AND RECRUITMENT STRATEGY

The target sample for this pilot study is up to 12 young people across Wales (both male and female) aged between 13-25 years, who either have a personal diagnosis of cancer or who have had current or recent experience of having a family member with cancer.

No participants will be directly approached by members of the research team for recruitment into the study, and the study will be advertised using a flyer/poster distributed through two main channels:

1) Existing Tenovus Channels: The study poster/flyer will be placed on the Tenovus website and sent out to Friends of Tenovus groups, Tenovus Sing With Us choirs and other support groups across South Wales linked to Tenovus. The flyer provides a brief overview of the study, graphical image of the virtual reality counselling world, and a contact project email address (c.evolve@sm.uwtsd.ac.uk) for obtaining further information about the study directly from the research team.

2) ABM University Health Board Cancer Services Departments: Posters and flyers (as above) advertising the study within appropriate and willing Cancer Services departments at Singleton Hospital, ABM University Health Board. Our project collaborator, Mrs Liwsi Kim Protheroe Davies, will act as the NHS R&D local collaborator for this site, although there is no direct involvement of NHS staff or resources in study recruitment or intervention delivery.

Additionally, the project flyer and study information will be sent to the Deputy Headmaster of the local comprehensive School in Swansea who have collaborated with Phase I of the project by providing young volunteers for the Young Persons Panel. Should the School, through the Deputy Head or Schools-based counsellor identify any pupils who they feel may be eligible they can signpost pupils/parents to the project flyer and email address.

The recruitment and consent process will involve three stages, as outlined below:

Stage 1: Initial Consent: Young people who are interested in taking part in the study can contact the research team via the project email address or telephone in order to receive further information about the study. If aged over 18 they will then be sent the study information sheet and consent form. If they remain interested in taking part they are asked to return the signed consent form to the research team within two weeks. If under the age of 18 they will receive a modified version of the consent form and will also need to obtain parental consent.

Stage 2: Eligibility Screening: The information sent to potential participants at the initial consent stage outlined above clearly states that in order to be eligible to take part in the study they will be required to complete questions assessing how they are currently feeling in order to make sure that online counselling is appropriate for them. Following the receipt of appropriate consent forms, the potential participant will be sent log in details to a specific page of the C:EVOLVE world, where they will be asked to complete the YP CORE screening questions. If they are deemed ineligible due to scoring over the cut-off score for psychological distress or failing to meet any other inclusion criteria, the project team will provide the individual with the option of being referred into the standard Tenovus counselling service, which currently offers counselling via telephone, Skype or if in the locality, face to face. In line with standard Tenovus practice, this may, after further assessment from the Tenovus Counselling Team, involve referral to the

person's GP, other cancer charities such as the Teenage Cancer Trust or ClicSargent that offer support to young people affected by cancer, or to a clinical psychologist. For participants under 18 years of age, the parent or guardian will be consulted as part of this process.

Stage 3: Access to online counselling: Once fully registered, the approved participant will be able to log on to the C:EVOLVE world through a unique password and username and re-confirm their consent into the study. They will then be able to create their avatar before the first online session is arranged using an online scheduler mechanism within the C:EVOLVE world, or email if preferred by the participant.

DATA COLLECTION AND MEASURES:

All measures have been carefully chosen as being considered appropriate for young people. They have been piloted for acceptability, ease of comprehension and readability by the volunteers in the Young Person's Panel in Phase I, and the time expected for completion of any of these combined measures at any given data collection time point is under ten minutes.

All data collection measures will be captured online through the SurveyGizmo tool, which will be linked to the virtual reality counselling world and completed as part of registration and counselling sessions (again, mirroring to a large extent the collection of evaluation data as standard practice at Tenovus). Following the final acceptance of the participant onto the study and the re-confirmation of final consent, participants will be asked to provide basic demographic details and key contact details at online registration (Time 0), before they are then able to create their avatar and arrange their first online counselling session. Participants will then be asked to complete brief pre-and post-online questionnaires at each counselling session (Time 1-Time 6). The final assessment will include further measures and will take place at the final six week counselling session, or after the last online counselling exchange if sooner e.g., if the participant decides to withdraw or to take up other alternative counselling provision. A summary of measures taken at each time point is provided below:

Measures taken at registration (Time 0)

Key demographic variables:

Demographic data will only be collected once participants have passed the initial screening process. At the registration stage following final consent into the study, key emergency contact information and basic demographic data on gender, age, ethnicity, region, whether personally affected or caring for someone with cancer, and whether undergone counselling previously will be collected. Questions from the existing Tenovus registration/screening form have been adapted for this purpose and this will be made available to the online counsellor prior to the first online session for each participant (the participant will have been made aware of this in the information sheet).

Pre-session measures:

Psychological functioning: Immediately prior to each session current levels of global psychological functioning will be captured through the Young Persons' CORE (Clinical Outcomes in Routine Evaluation) assessment system. CORE is currently used by Tenovus (and many other counselling services) to evaluate the outcomes of counselling and assess the functioning of a client before each session. The YP CORE is a brief ten-item version of this scale created to produce a user-friendly measure of change in school and youth-based counselling services that is easy to comprehend and has been shown to have good psychometric properties (Sefi and Hanley, 2012). The YP-CORE has been used to measure effectiveness of online counselling for young people (Sefi and Hanley, 2012). For the purpose of the current study a cut-off point of 20 representing severe levels of distress has been selected. Given the nature of this feasibility study and in accordance with BACP guidelines on online therapy, for the young people who are in immediate distress and/or presenting a severe issue it may be more appropriate to offer alternative support through Tenovus.

Mood and emotional state: In order to capture specific emotions and general mood of participants immediately prior to each counselling session (Time 1 to Time 6), participants will also be asked to complete the emotions scale of the Session Evaluation Questionnaire (Stiles, 1980). This scale is a simple 7-point bipolar adjective scale capturing ten dimensions of current emotion/mood.

Post-session measures after each session:

The Session Evaluation Questionnaire (Stiles, 1980) will be used to evaluate the impact of the session and the participants' mood and emotional state immediately after every online session. Using two simple 7-point bipolar adjective scales, the SEQ evaluates the counselling session across 11 dimensions (which can be totalled to capture overall smoothness and depth of the session), and the participant's emotions/mood following that session (which can be totalled to produce scores for overall positivity or arousal). Each item is scored from 1 to 7, reversed as appropriate, with higher scores indicating greater Depth, Smoothness, Positivity, or Arousal. The SEQ is typically completed by participants immediately following the session to be evaluated and has been applied to many types of individual and

group sessions (Stiles, 1980; Stiles, Reynolds, et al., 1994; Stiles & Snow, 1984b; Stiles, Tupler & Carpenter, 1982; Stiles, Gordon, & Lani, 2002). The SEQ has been piloted with the Young Persons Panel in Phase I for ease of readability and completion.

An adapted version of the Post Counselling Evaluation questionnaire from the Welsh Government School Based Counselling Tool Kit (2011) will be used to identify the therapeutic relationship between the participant and the counsellor during the online sessions. An additional short questionnaire will assess participants' views about the ease of use of the virtual reality world and technical elements of the intervention, with a free text provided for optional additional comments.

In addition to the quantitative data collected through the questionnaires, the mechanisms of this intervention will also enable the digital capture of data relating to the selection of specific emotional responses through each counselling session. This will allow us to track the frequency and intensity of emotional changes during and across different counselling sessions, and to also evaluate the reliability/validity of the digital emotional responses of participants by comparing them to key data captured through explicit questionnaire measures.

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.

The final design of the intervention being piloted in Phase II (the current protocol) has been informed by the on-going input/feedback provided by a Young Person's Panel of young people aged between 15 and 21 throughout Phase I of the study. Following NHS ethical approval for Phase 1, volunteers for the Young Person's Panel were recruited from students at Swansea Metropolitan University (n=4) and from a local comprehensive school (n= 8). The Young Person's Panel have met monthly (facilitated by members of the Project Team) to provide feedback on the virtual reality world as it developed. Four meetings have taken place at this point with a further two planned before the end of the year. Alongside contributing to the design of the virtual reality world (for example, voting on preference for avatar design and testing out the interface), the YPP were also asked to discuss wider issues such as the meaning of counselling and what young people would expect from a virtual reality counselling session. The YPP have piloted all of the recruitment materials prepared for Phase II (the current protocol) and where difficulties were noted the materials have been amended accordingly. Finally, the YPP also contributed to online discussions via a closed Facebook page set up for the project and moderated by the CI and project RA on a daily basis.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

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

- Young people (male and female) aged 13-25 years across Wales
- Young people with a personal diagnosis of cancer
- Young people with current or recent experience of having a family member with cancer
- Young people with access to a safe and secure internet connection

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

- Young people who score more than 20 on the CORE YP during initial screening which suggests high levels of psychological distress requiring referral to established counselling pathways (via Tenovus in the first instance).
- Young people who are not fluent English speakers
- Young people already receiving counselling from another support organisation (this is standard practice amongst most counselling organisations)

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	1		30mins	CI and the research assistant
Pre-session Questionnaires	1		10mins	this will be completed online by the participant, Guidance will be provided online
Post-session Questionnaires	1		10mins	this will be completed online by the participant, Guidance will be provided online
Online counselling sessions	6		1hour	This will be conducted online between the participant and a qualified counsellor
Avatar development and registration	1		60 mins	this will be conducted online by the participant, Guidance will be provided online

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

Participants will be able to receive up to six weeks of online counselling during the course of this study (mirroring standard practice currently offered by Tenovus for face-to-face counselling). It is therefore anticipated that the maximum amount of time a participant will be involved in the study in total from the initial consent process and up to receipt of a thank you letter will be a maximum of six 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.

SAFEGUARDING THE CHILD IN AN ONLINE COUNSELLING ENVIRONMENT

The British Association for Counselling and Psychotherapy (BACP) has proposed a number of ethical considerations in relation to the delivery of online counselling. In addition to the policies outline above, the general BACP guidelines (2013) and the Welsh Assembly School-Based Counselling policies (2011) have been consulted in order to identify the following set up good practice guidelines for this study in terms of the delivery of online counselling and protection of young people within this virtual environment.

IDENTIFYING THAT THE ONLINE COUNSELLING IS APPROPRIATE FOR THE PRESENTING CONCERN:

BACP guidelines emphasis the importance of ensuring that the concerns and issues presented by potential clients are considered appropriate for online counselling. Given the remit of this feasibility study, this will be achieved in the current study through undertaking the initial screening assessment using the YP-CORE cut off score of 20 to identify young people with more severe levels of distress. Individuals who exceed this cut-off score will be offered the opportunity to be referred into standard Tenovus counselling options (Skype, telephone or face-to-face counselling) or to another counselling organisation or clinical psychologist if deemed more appropriate by the Tenovus counselling service.

MAINTANING CONFIDENTIALITY AND PRIVACY ISSUES DURING ONLINE COUNSELLING:

To maximise the security of the C:EVOLVE world, the programme will use encryptions and firewalls that protect

information from hackers or malware. The content of the sessions and any communication and materials will be password protected. The C:EVOLVE online counselling will also use the university's firewalls to protect against harmful viruses that can be received from or transmitted to others, including clients.

Maintaining confidentiality and privacy of the content of counselling is an important ethical issue in online counselling which will be addressed within the informed consent process. It is made clear in the study information sheet that the content of the online counselling sessions themselves will not be made available to anyone in the research team and will not be published or analysed for any research purposes.

However, in line with appropriate policies, it is also made clear to study participants in the informed consent stage that absolute confidentiality of the content of the counselling sessions cannot be guaranteed, as the welfare of the young person will at all times take precedence over confidentiality. The information sheet includes the statement regarding the potential disclosure of information to a Designated Child protection Person, if the counsellor has knowledge, concerns or suspicions that a child is suffering or is likely to be at risk of harm. Additionally, as is standard practice amongst practicing counsellors, it is indicated in the study information sheet that the counsellor may choose to discuss some aspects of the online counselling sessions with their own supervisor.

MINIMISING HARM/DISTRESS

It is important to acknowledge that in the context of the current study that the very nature of the problems that the participants present with during their online counselling sessions means that some level of psychological discomfort or distress is likely to be unavoidable. Indeed, the process of counselling often involves a "working through" of problems over time, and some increases in anxiety, worry or distress in the early stages of counselling are often a natural part of the therapeutic process. The procedure for minimising and monitoring potential harm during online counselling, will, wherever possible, mirror the robust procedures put in place in Tenovus for their face-to-face counselling sessions. The recruitment of a BACP-registered counsellor (see section 6.4) will ensure that the counsellor is comfortable and experienced with dealing with clients in crisis and is aware of appropriate response and referral options were necessary.

The capture of data relating to participants' psychological functioning and emotional changes over the course of the pilot study will enable the research team to monitor any evidence of the intervention making people highly distressed. Should any evidence of extreme distress be apparent that the counsellor feels unable to deal with due to the confines of online counselling, the individual will be referred through to the Tenovus counselling service in order to identify appropriate action and the project steering group will be convened to discuss the potential implications of this for the continuation of the study.

During the online counselling session itself, participants will be able to pause or exit the session at any time by pressing a simple button should they not wish to continue the session. Pressing the "pause" button will create an unreadable "blurred" version of the C:EVOLVE world to ensure confidentiality of the online session in the event that the session has been paused due to interruption or the need for the participant to leave the screen momentarily. The session can be restarted with a simple "continue session" button and by re-entering the password.

If the participant does select the "exit" option at any time, a pop-up screen will appear reminding participants of how to make contact with the counsellor or research team if there are specific issues they wish to discuss, and reminding participants that the counsellor may decide to contact their emergency contact details if they are concerned about their welfare or that of others. They will also be provided with the contact number for further support and advice from Tenovus if they so choose at any point.

FRUSTRATIONS CAUSED BY INTERRUPTION OF THERAPY DUE TO TECHNICAL ISSUES:

The potential of interrupting therapy due to technological problems is a concern in online counselling. In the event that a session is interrupted due to a power or connection problem, the counsellor will call the client. If the client does not receive a call within ten minutes of the disconnection or error, they can email or call the project team who will be on site at UWTSD at that time in order to liaise with the IT support function. If the connection is not restored they will be offered an alternative appointment and the opportunity to finish the session via telephone counselling or email. Information about what to do if an interruption happens and other technical issues will be given to participants a Frequently Asked Question page provided prior to the first online session.

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:

In the context of the current study, the very nature of the problems that the participants may present with during their online counselling sessions means that some level of psychological discomfort or distress is likely to be unavoidable. Whilst it has been made clear to all participants in the Study Information Sheet that they can withdraw from the study at any time should they not wish to continue, it is considered essential to ensure that any such individuals are provided with the opportunity for alternative forms of support if needed. Accordingly, any participant who does withdraw from the study at any time will be provided with the opportunity to be referred into Tenovus to assess suitability for other forms of counselling offered.

The process of counselling often involves a "working through" of problems over time, and some increases in anxiety, worry or distress in the early stages of counselling are often a natural part of the therapeutic process. The procedure for minimising and monitoring potential harm during online counselling mirror as closely as possible the robust procedures put in place in Tenovus for their face-to-face counselling sessions. The recruitment of a BACP-registered counsellor with experience of working with young people will ensure that the counsellor is comfortable and experienced with dealing with clients in crisis and is aware of appropriate response and referral options were necessary.

As described in A22, during the online counselling session itself, participants will be able to pause or exit the session at any time by pressing a simple button should they not wish to continue the session.

Finally, the capture of data relating to participants' psychological functioning and emotional changes over the course of the pilot study will enable the research team to monitor any evidence of the intervention making people highly distressed. Should any evidence of extreme distress be apparent that the counsellor feels unable to deal with due to the confines of online counselling, the individual will be referred through to the Tenovus counselling service in order to identify appropriate action and the project steering group will be convened to discuss the potential implications of this for the continuation of the study.

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

As this is a pilot study, we are not certain about the potential for benefit to research participants, and this is made clear to potential participants in the study information sheet.

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

There is no significant risk for the researchers at Phase II of the research study as the counselling will be delivered online. The online counsellor will receive weekly supervision in line with standard practice.

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 Research Team is not identifying any potential participants or directly targeting individual participants. The project team wish to advertise the study through:

- 1) Tenovus dissemination channels e.g. through their website and flyers sent to existing "friends of Tenovus".
- 2) Posters and flyers advertising the study within the Cancer Services department at Singleton Hospital, ABM University Health Board
- 3) Via information sent to the Deputy Head of Olchfa Comprehensive School

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:

Given the non-intrusive recruitment strategy, there will be no requirement or opportunity to identify potential participants or access personal information prior to consent.

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).

A poster/flyer has been created in order to advertise the study. The advert provides a brief overview of the study, graphical image of the C:EVOLVE virtual reality counselling world, and a contact project email address (c:evolve@sm.uwtsd.ac.uk) and telephone number for obtaining further information about the study directly from the research team.

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

Potential participants will not be directly targeted but will need to contact the research team to express an interest in taking part. They will then be sent the study information sheet and consent form(s) by email or post as requested.

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.

Informed consent forms from the research participants will be obtained in three stages.

Stage 1: Initial Consent: Young people who are interested in taking part in the study can contact the research team via the project email address or telephone in order to receive further information about the study. If aged over 18 they will then be sent the study information sheet and consent form. If they remain interested in taking part they are asked to return the signed consent form to the research team within two weeks. If under the age of 18 they will receive a modified version of the consent form and will also need to obtain parental consent.

Stage 2: Eligibility Screening: The information sent to potential participants at the initial consent stage outlined above clearly states that in order to be eligible to take part in the study they will be required to complete questions assessing how they are currently feeling in order to make sure that online counselling is appropriate for them. Following the receipt of appropriate consent forms, the potential participant will be sent log in details to a specific page of the C:EVOLVE world, where they will be asked to complete the YP CORE screening questions. This assessment of whether potential participants have met the eligibility criteria will be completed by two suitably qualified members of the project team (Dr Ceri Phelps and Carol Hughes) within 24 hours of the questions being completed. The potential participant will then be informed via email or telephone (as per their stated preference) as to whether they are eligible to complete the full registration phase and join the study.

If they are deemed ineligible due to scoring over 20 on the YP CORE or failing to meet any other inclusion criteria, the project team will provide the individual with the option of being referred into the standard Tenovus counselling service, which currently offers counselling via telephone, Skype or if in the locality, face to face. In line with standard Tenovus practice, this may, after further assessment from the Tenovus Counselling Team, involve referral to the person's GP, other cancer charities such as the Teenage Cancer Trust or ClicSargent that offer support to young people affected by cancer, or to a clinical psychologist. For participants under 18 years of age, the parent or guardian will be consulted as part of this process.

Stage 3: Access to online counselling: Once fully registered, the approved participant will be able to log on to the C:EVOLVE world through a unique password and username and re-confirm their consent into the study. They will then be able to create their avatar before the first online session is arranged using an online scheduler mechanism within the C:EVOLVE world, or email if preferred by the participant.

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

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

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

☒ Yes ☐ No

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

Participants will be given two weeks from the date they receive the Study Information Sheet to decide whether or not to take part. They will be asked to return the signed consent form to the project team if they decide to take part in the project. If no response is received from potential participants within two weeks, one simple follow-up email will be sent to check that the information was received and to remind them of the steps needed to consent into the study if they do wish to do so.

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)

Due to the nature of this feasibility project it will not be appropriate to recruit individuals without sufficient understanding of English or with special communication needs.

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?

Again, due to the nature of this feasibility project it will not be appropriate to recruit individuals wishing to participate through the the medium of Welsh.

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
- ☒ 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 including X-rays
 - ☐ NHS computers
 - ☐ Home or other personal computers
 - ☒ University computers
 - ☐ Private company computers
 - ☐ Laptop computers

Further details:

The counsellor may keep her/her own notes about the counselling session and participant's progress, and these will be stored confidentially in accordance with standard BACP guidelines.

In some cases personal data from the participants (contact details, basic demographics and their baseline YP-CORE) score may be passed on to Tenovus or to a designated authority (e.g., schools-based counsellor, child protection officer) if deemed necessary. This has been outlined to participants in the study information sheet.

All other data will remain stored on secure University networks in locked filing cabinets on University premises as appropriate.

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

All data gathered will be confidential. Participants will be given a unique username ID to engage with the C:EVOLVE world, which will be linked to consent forms using a master secure identification key and locked and stored in a separate filing cabinet from the consent forms (and emergency contact detail forms) themselves in the CI's office.

Completion of the online questionnaire at each time point will be linked to this unique username and an additional ID number. Once the data is downloaded onto SPSS the ID number alone will be used, with access to any saved data being password-protected on a secure university network. A master list of ID numbers and participant names will be kept in a separate locked drawer in the researcher's office.

No personal data from the counselling sessions themselves will be used in any research report or analysis, and the content of the sessions and any communication and materials will be password protected.

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.*

This study will not involve access to any medical or clinical notes.

The initial background screening measure of psychological functioning and key background information (e.g. previous use of counselling, key demographics) will be available only to the CI, research assistant, and online counsellor, and this is made clear in the study information sheet.

The counsellor may keep his/her own written record of the progress of the counselling which will be stored confidentially as per standard BACP guidelines.

Only the anonymised data in SPSS will be made available to key members of the research team for the purposes of analysis.

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.

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)

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.

Project participants will be offered to receive a summary of the findings when they receive a thank you letter after the last counselling session.

5. Scientific and Statistical Review

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

- ☒ Independent external review
- ☐ Review within a company
- ☐ Review within a multi-centre research group
- ☒ Review within the Chief Investigator's institution or host organisation
- ☒ Review within the research team
- ☐ Review by educational supervisor
- ☐ Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:

The study has undergone scientific review by the funding body's Scientific Advisory Committee as part of their peer review process.

The study has also been reviewed by Swansea Metropolitan University's School of Psychology and Counselling Research Ethics Committee.

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
	Dr Paul Hutchings
Department	BSc, MRes, PhD (Cardiff), CPsychol, AFBPsS
Institution	University of Wales Trinity St David, Swansea
Work Address	School of Psychology & Counselling, Faculty of Social Sciences University of Wales Trinity St David, Swansea
Post Code	SA2 0UT
Telephone	01792482080
Fax	
Mobile	
E-mail	paul.hutchings@sm.uwtsd.ac.uk

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

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

The primary outcome measures for phase II of this study is to explore whether psychological functioning has improved in participants from the baseline (Time 1) assessment to the final (Time 6) assessment (following six weeks of online counselling) using the YP CORE.

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

Secondary outcome measures will include:

- 1) Changes in mood and emotional state using the emotions scale of the Session Evaluation Questionnaire (Stiles, 1980), a simple 7-point bipolar adjective scale capturing ten dimensions of current emotion/mood, and also the digitally collected emotional responses.
- 2) Satisfaction with counselling and the therapeutic relationship using the impact scale of the Session Evaluation Questionnaire (Stiles, 1980) which evaluates the counselling session across 11 dimensions (which can be totalled to capture overall smoothness and depth of the session).
- 3) Post counselling evaluation of therapeutic relationship, measured through an additional 11-item questionnaire adapted for online counselling (taken from the example evaluation form from the Welsh Government School-based Counselling Operating Toolkit, 2011).
- 4) Process evaluation measures: A bespoke brief questionnaire will be used to identify the participants' views about the ease of use of the virtual reality world and technical elements of the intervention, with a free text provided for optional additional comments.
- 5) Perceptions of the online counselling world from the Counsellor's Perspective: In order to capture the experience of delivering counselling through a virtual reality counselling world, the counsellor will be asked to maintain a reflective diary through the duration of Phase II. This reflective diary will focus on their perceptions of the efficacy of the counselling, their experience of avatar-based counselling, and working alliance in online counselling.

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: 12

Total international sample size (including UK):

Total in European Economic Area:

Further details:

Please see A60 below

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 target sample for this pilot study is up to 12 young people (both male and female) aged between 13-25 years. Given the nature of this feasibility study it is considered prudent to exercise a cautious staggered approach to study recruitment, monitoring a smaller number of participants carefully over time rather than recruiting en masse at the start of the study (which would also cause potential problems for the individual delivering the counselling given the novelty of this intervention).

A61. 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.

Data from the online questionnaires will be entered into SPSS v19.

Given the small number in this pilot study and the need to closely monitor the potential impact of the intervention over time within individuals, much of this analysis will explore case-by-case changes amongst individuals. It is unlikely that the study will have sufficient numbers of participants or power to enable parametric analysis of variance of changes over time over multiple time-points, and the most suitable non-parametric alternative (Kruskal-Wallis Test of multiple changes over time, or Wilcoxon Signed Rank Test on Time 1 – Time 6 scores) will be conducted if final numbers allow.

Secondary outcomes will include changes in emotion and mood before and after each session, which will be analysed using a related t-test or non-parametric equivalent at each time-point. The emotions will also be descriptively analysed using frequencies and mean scores, and compared to the digitally collected emotions data for an exploratory validity analysis to identify whether future studies could reliably use digitally captured emotional responses as a valid outcome measures.

Finally, a descriptive analysis of the uptake and retention rates, and demographic profile of participants to the questions measuring ease of use and satisfaction with the technical aspects of the intervention will be carried out. If numbers allow, analyses will also explore any differences in demographics or psychological functioning in participants who drop out of the pilot study versus those who complete the six weeks of online counselling.

Any free text data provided by participants will be analysed thematically by hand, as will the qualitative data from the reflective diaries. This data will be analysed using a thematic narrative analysis (Tighe et al. 2011; Ross and Green 2011) which will enable a critical qualitative analysis of the experience of engaging with the online counselling world from the perspective of the counsellor.

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

Mr Andrew Baker

Post Senior Lecturer

Qualifications BSc Computer Games Development
BA Creative Computer Games Design
BSc 3D computer Animation

Employer University of Wales Trinity St David, Swansea

Work Address School of Applied Computing
Mount Pleasant
University of Wales Trinity St David, Swansea

Post Code SA1 6ED

Telephone 01792481000

Fax

Mobile

Work Email andrew.baker@sm.uwtsd.ac.uk

Title Forename/Initials Surname
Ms Carol Huges

Post Senior Lecturer

Qualifications BA Hons (University of Wales)
MPhil (Swansea Metropolitan University)

Employer University of Wales Trinity St David, Swansea

Work Address School of Psychology & Counselling
Faculty of Social Sciences
University of Wales Trinity St David, Swansea

Post Code SA2 0UT

Telephone 01792481000

Fax

Mobile

Work Email carol.hughes@sm.uwtsd.ac.uk

Title Forename/Initials Surname
Dr Paul Hutchings

Post Psychology Programme Director

Qualifications BSc, MRes, PhD (Cardiff), CPsychol, AFBPsS

Employer University of Wales Trinity St David, Swansea

Work Address School of Psychology & Counselling,
Faculty of Social Sciences
University of Wales Trinity St David, Swansea

Post Code SA2 0UT

Telephone 01792482080

Fax

Mobile

Work Email paul.hutchings@sm.uwtsd.ac.uk

Title Forename/Initials Surname
Mrs Helen French

Post Counselling Services Manager

Qualifications Post-graduate Diploma, Consultative Supervision
Post-graduate Diploma, Counselling Children & Young people.
Advanced Diploma in Therapeutic Counselling
Certificate in Counselling Studies

NVQ Management level 4

Employer Tenovus Counselling Services

Work Address Tenovus
9th floor, Gleider House Ty Glas Road
Cardiff

Post Code CF14 5BD

Telephone 02920 520218

Fax

Mobile 07794 225254

Work Email Helen.French@tenovus.org.uk

Title Forename/Initials Surname
Dr Masoumeh Minou

Post

Qualifications BA (Hons)
MSc
PhD

Employer University of Wales Trinity St David, Swansea

Work Address School of Psychology & Counselling,
Faculty of Social Sciences
University of Wales Trinity St David, Swansea

Post Code SA2 0UT

Telephone

Fax

Mobile

Work Email mas.minou@sm.uwtsd.ac.uk

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

☐ Local Authority

☐ Other social care provider (including voluntary sector or private organisation)

☐ Other

If Other, please specify:

Contact person

Name of organisation University of Wales Trinity St David, Swansea Metropolitan

Given name Gwndaf

Family name Tobias

Address Mount Pleasant Campus

Town/city Swansea

Post code SA1 6ED

Country UNITED KINGDOM
Telephone 01792481000
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 Gleider House
Ty Glas Road
Cardiff
Post Code CF14 5BD
Telephone 02920768850
Fax
Mobile
Email anita.howman@tenovus.org.uk

Funding Application Status: ☒ Secured ☐ In progress

Amount: £28K

Duration

Years: 1

Months:

If applicable, please specify the programme/ funding stream:

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

Tenovus Innovation Grant Scheme

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

☐ Yes ☒ No

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

A68-1. Give details of the lead NHS R&D contact for this research:

	Title Forename/Initials Surname
	Ms Kirsty Price
Organisation	Abertawe Bro Morgannwg University Health Board
Address	Morriston Hospital
	Morriston
	Swansea
Post Code	SA6 6NL
Work Email	kirsty.price4@wales.nhs.uk
Telephone	01792704056
Fax	01792545774
Mobile	

Details can be obtained from the NHS R&D Forum website: <http://www.rdforum.nhs.uk>

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

Planned start date: 01/12/2013

Planned end date: 31/05/2014

Total duration:

Years: 0 Months: 5 Days: 31

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. What host organisations (NHS or other) in the UK will be responsible for the research sites? Please indicate the type of organisation by ticking the box and give approximate numbers of planned research sites:

☐ 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
- ☐ Social care organisations
- ☐ Phase 1 trial units
- ☐ Prison establishments
- ☐ Probation areas
- ☐ Independent hospitals
- ☒ Educational establishments
- ☐ Independent research units
- ☐ Other (give details)

1

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 Wales Trinity Saint David's insurance arrangements will apply.

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 Wales Trinity Saint David's insurance arrangements will apply.

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 Wales Trinity Saint David's insurance arrangements will apply.

Please enclose a copy of relevant documents.

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.**

The potential age range of children under 16 who will be included in this research study is 13-16. As this project is funded by Tenovus, it follows Tenovus's desire to create an online counselling service targeted at 13-25 year olds.

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

N/A

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.

Upon receipt of an expression of interest from a potential participant or parent/guardian, the study information sheet, parental consent form, and young persons form will be emailed or posted out. The young person and parent/guardian will be given two weeks to read the information provided, discuss the young person's participation in the project and ask any questions they might have from the research project members (contact details are provided on the Participant Information Sheet). Upon receipt of signed consent forms from both the parent and the young person, the lead researcher will make telephone contact with the parent to verify the consent given.

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.

The Participant Information Sheet has been designed to present information for children under 16 in an easily understandable manner and has been piloted by the Young Person's panel at Phase I for its ease of understanding, sensitivity of content, clarity and friendly-user aspect. In particular, Part One of the information sheet has been kept as simple as possible so that young people should be able to read this themselves and understand the study, whilst it is recommended that Part Two is discussed with their parent/guardian. The study information sheet has been put through the Flesch Reading Ease to ensure a minimum readability score of 70 where possible.

The Participant Information Sheet has been produced in line with the National Research Ethics Service Information Sheets & Consent Forms Guidance for Researchers & Reviewers.

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	University of Wales Trinity Saint David, Swansea	Title	Dr
Department name	School of Psychology & Counselling	First name/ Initials	Ceri
Street address	Townhill Campus	Surname	Phelps
Town/city	Swansea		
Post Code	SA2 0UT		

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: Dr Ceri Phelps

Date: 21/10/2013 (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.
6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.
7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Signature:

Print Name: Mr Gywndaf Tobias

Post: Pro Vice Chancellor (Finance and Planning)

Organisation: University of Wales Trinity Saint David

Date: (dd/mm/yyyy)