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Developing and testing a theory-driven e-learning intervention to equip healthcare professionals to communicate with parents impacted by parental cancer

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ABSTRACT

Purpose: Parents have a desire and need for instructive support from healthcare professionals on how best to communicate a cancer diagnosis with their dependent children. Healthcare professionals lack confidence to initiate and facilitate parent-child communication, reporting the need for training. To address the evident gap, this paper outlines the planning, development and testing phases of an e-learning intervention, using a person-based approach.

Methods: The planning and development phases combined evidence from reviews of qualitative and quantitative literature, an expert group and data generated from primary research of two focus groups with frontline oncology professionals (n = 23) to develop the e-learning intervention prototype.

An iterative approach was adopted with 14 'think aloud' interviews for prototype usability testing, resulting in continuous movement between data collection, analysis and modification of the e-learning intervention.

Results: Involving end-users throughout all phases of this process, optimised the intervention development. As a result, a communication framework on how healthcare professionals can initiate these conversations with parents was integrated, alongside role-play videos and original artwork by children expressing their views associated with parental cancer.

During the testing phase, think-aloud interviews identified key navigational difficulties which were modified and resolved. Minor modifications were made to the content and 'look and feel' of screen pages.

Conclusions: The systematic and iterative, person-based approach, yielded important and complementary insights to enhance acceptability of the e-learning intervention. Providing a detailed description of the foundations that underpinned the development of this e-learning intervention, promotes transparency in the planning and design process, therefore aids methodological rigour.

1. Introduction

Lack of communication surrounding a parent's cancer diagnosis is associated with increased levels of psychological distress for children, with some developing serious problems, such as separation anxiety, anger, depression, sleep disturbance, difficulties with school and lower self-esteem (Morris et al., 2016; Hasson-Ohayon and Braun, 2011). Whereas, open and honest communication surrounding parental cancer, leads to improved family cohesion and reduced psychosocial distress for both parents and children (Forrest et al., 2006).

Parenting is a primary focus of everyday activity for adults who have young children but when a parent is diagnosed with cancer this poses unique challenges for families. At this distressing time, parents often struggle to know how best to meet their children's emotional needs (Semple and McCance, 2010). Prior research reports that parents are not well supported by oncology professionals in how best to manage, communicate with and support their children and clearly many would benefit from guidance and advice about parenting during cancer (Niemelä et al., 2010; Semple and McCaughan, 2013). With increased survival rates for cancer patients and the changing demography of families across the globe having children later in life, healthcare professionals (HCPs) can anticipate providing care for a growing number of people with cancer who will also be caring for dependent children (O'Neill et al., 2016).

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HCPs in frontline oncology roles are well placed to guide parents on how best to tell children about parental cancer and support them at this critical juncture. Despite HCPs' willingness to support families in this challenging and vulnerable situation, research highlights HCPs lack knowledge, confidence in their skills and training surrounding this important aspect of care (Cathcart, 2008; Grant et al., 2016; Semple et al., 2017). In a recent study, most HCPs (over 90%) working in an oncology setting, reported having no formal training on how to support patients with cancer who have young children (Semple et al., 2017). Without adequate education, oncology professionals can experience greater emotional distress, which can have an impact on their wellbeing (Jenkins and Fallowfield, 2002). Despite increasing recognition of the impact of parental cancer on the family unit, alongside parents' desire for instructive support from healthcare professionals, intervention research lags behind the descriptive literature. To address this gap, there is a need to provide HCPs with education and training to promote confidence in their ability to initiate and facilitate parent-child communication and supportive care when a parent has cancer.

As previously noted, educational interventions for HCPs on this aspect of care is very limited (Semple et al., 2017; Grant et al., 2016; Turner et al., 2009). Furthermore, the mode of delivery for each intervention has been face-to-face. Due to ongoing demands on HCPs time in the clinical setting, they not only desire but expect education to be delivered in a way that offers increased usability and convenience (Palfrey and Gasser, 2013). The use of e-learning is a rapidly growing and evolving way of delivering education, generally (Digital Agenda Assembly, 2001; Commission of the European Communities, 2000, 2001). E-learning refers to the use of internet technologies to deliver a broad array of solutions that enhances knowledge and performance (Rosenberg, 2001). The rapidity of growth in e-learning is also evident within the healthcare setting. It has been described as a dynamic, innovative and rich way to provide convenient learning opportunities (Lahti and Välimäki, 2009; Cook et al., 2010; Belcher and Vonderhaar, 2005), enabling the learner to balance professional development with personal and work commitments (Sinclair et al., 2014). In general, the benefits reported for e-learning are flexibility, accessibility, satisfaction and cost-effectiveness due to enabling wide reach with low operational costs (Smith, 2005; Wutoh et al., 2004, Brace-Govan & Gabbott, 2004). In addition, the available evidence suggests that online learning in healthcare is equally effective for acquisition of skill, knowledge, self-efficacy and clinical confidence, as the traditional means of face-to-face learning (McCutcheon et al., 2015).

Despite a clear trend towards increased availability of e-learning interventions for HCPs internationally, the development and evaluation process is often not clearly described in sufficient detail to enable replication. Furthermore, a recent systematic review outlined that many e-learning interventions devised for clinicians are not developed based on theory (Sinclair et al., 2016). In order to develop e-learning interventions which are more likely to be effective, sustainable and scalable, there is a need to ensure they are evidence-based and theory driven, hence careful attention given to intervention planning, product design and testing.

This paper will outline, in detail, the development of a theory-based, interactive e-learning module for HCPs using a person-based approach (Yardley et al., 2015a), to enhance HCPs self-efficacy when supporting parents newly diagnosed with cancer who have dependent children. This paper will not only enable readers to gain an insight into the decision-making process of the team, at each step of the planning, design and testing phases but will also provide a template to guide the development of other theory-based evidence-based e-learning interventions, using the person-based approach. To the authors knowledge this is the first study to report on the development of an online educational programme, suitable for a wide range of HCPs working in oncology to enhance the supportive care of patients and families when a parent has cancer.

2. Aim

To develop and test an e-learning intervention, using a person-based approach, to enhance HCPs self-efficacy when supporting parents newly diagnosed with cancer to communicate with their children.

2.1. Design of the study

This study used a person-based approach which provides an explicit, rigorous and systematic process for intervention development, emphasing the importance of end-user involvement and iterative testing to promote acceptability and effectiveness (Yardley et al., 2015b). The person-based approach has two core elements. Firstly, it advocates generating in-depth understanding with intervention users through iterative use of qualitative research. In conjunction with the findings of this primary research, other evidence is correlated, to include reviews of relevant qualitative and quantitative literature and expert opinion. This step in the person-based approach will produce a detailed understanding of the likely barriers and facilitators to intervention implementation. The second core element is to produce 'guiding principles', which identifies i) the main intervention design objectives in terms of behaviour change and outcomes and ii) describes the key features of the intervention required to achieve each objective.

The planning, development and testing process of this e-learning intervention will be covered in four phases. Phase one outlines the theory and evidence generated to plan the intervention. Phase two details how primary qualitative research was also used as part of intervention planning. Iteratively using the data generated from the first two phases, the third phase presents how a collaborative working group designed and refined the content and delivery of the e-learning intervention with the use of 'guiding principles'. Finally, the fourth phase reports on the usability testing of the e-learning intervention using think-aloud interviews. These four phases are illustrated in Fig. 1.

This study is reported following the COREQ guidelines (Torg et al 2007).

2.2. Participants and procedures

Focus groups (n = 2, group one = 16 participants, group 2 = 7 participants) and one-to-one think-aloud interviews (n = 14) were conducted by the first author (CS, nurse researcher), at HCPs place of work and during their working hours. Participants were purposively recruited to sample a diverse range of professional backgrounds who had experience of providing care for parents newly diagnosed with cancer to include staff nurses, specialist nurses, social workers, psychologist, counsellors, art therapist, managers in cancer care, allied health professionals (AHP); working within the acute and community settings, encompassing both the statutory and voluntary sectors in Northern Ireland, UK. Written consent was obtained, and all interviews were recorded using a digital voice recorder and transcribed. Data was collected from May 16 – April 17.

The study was approved by the Research Ethics Committee for Northern Ireland (IRAS project number 209312).

2.3. Analysis

Analysis began after the first focus group was conducted, utilizing an iterative approach to guide the planning of the content and design. For the think-aloud interviews, data analysis commenced on completion of the first interview and continued until completion of all 14 think-aloud interviews. Thematic analysis was conducted for these primary qualitative studies (Miles & Huberman 1994).

The following sections describe the methods used and findings for each of the phases.

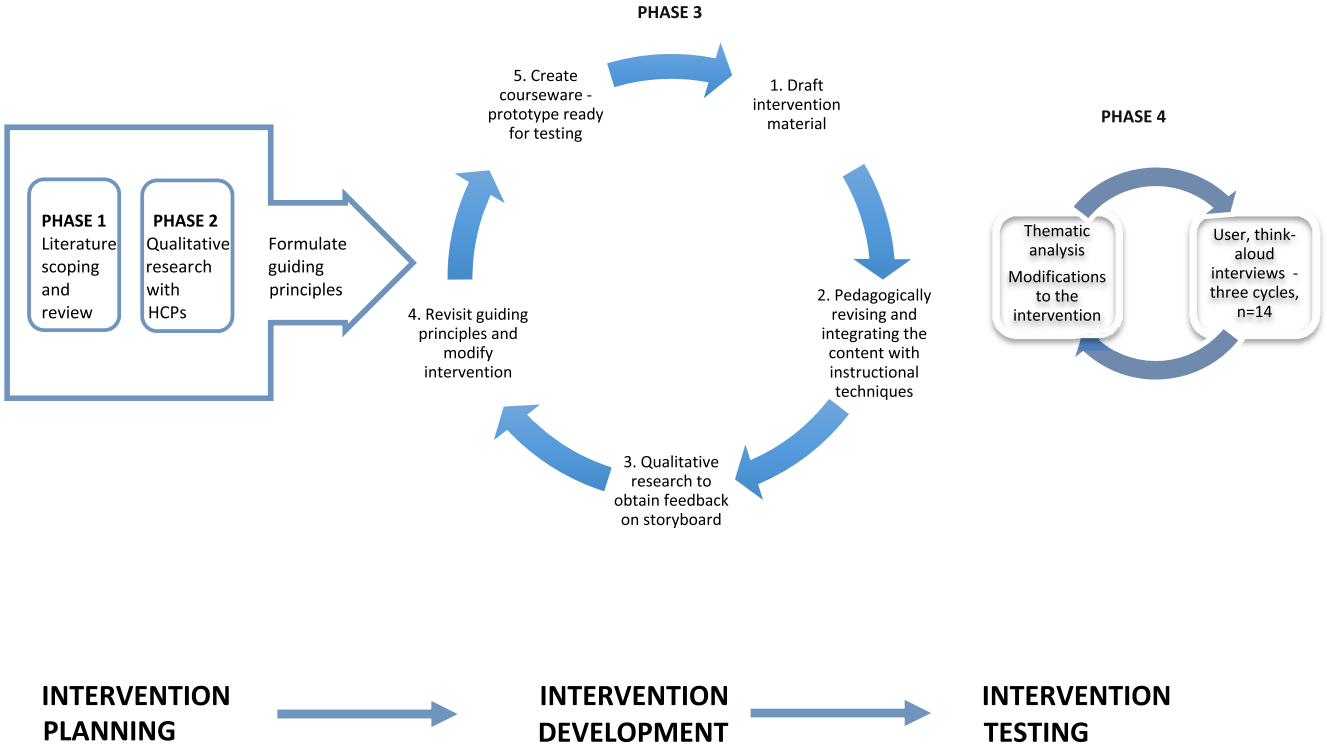

Fig. 1. Diagram outlining the phases undertaken to develop the e-learning intervention, using the person-based approach.

3. Intervention planning

3.1. Phase 1: establishing a theory-based and evidence-based approach to intervention development

There is widespread consensus that systematic intervention planning incorporating existing theory, evidence and the views of potential users is key to creating interventions which will be successful and widely adopted into practice (Bradbury et al., 2014). The research team had recently developed, delivered and evaluated a theory-based and evidence-based, face-to-face educational intervention for frontline oncology professionals on supporting families when a parent is diagnosed with cancer, which informed intervention planning. This is described only briefly below, as it is published in more detail elsewhere (Semple et al., 2017).

This face-to-face educational intervention was centred on existing literature and the principles of social, cognitive and modelling theory to promote change of thought, feeling, and attitudes when professionals are supporting parents newly diagnosed with cancer (Semple et al., 2017). It was deemed appropriate to adopt the same theoretical approach for this e-learning, given a similar target audience and evidence of improved perceived levels of confidence and competence to communicate with patients about parental cancer, following the education session (Semple et al., 2017).

For others teams using the person-based approach, who are not developing their intervention as part of an ongoing programme of work, it may be necessary and advantageous at this intervention planning phase to conduct a rigorous synthesis of existing theory and evidence to underpin and inform intervention development. This process can provide helpful insights into the intervention components that have the potential to be desirable, feasible and salient to promote engagement and effectiveness (Yardley et al., 2015a).

3.2. Phase 2: Qualitative research with users and stakeholders to identify intervention component

Once theoretical foundations and preliminary content was mapped out, the next step, guided by the person-based approach, was to conduct qualitative research to extrapolate the views and opinions of end users of the e-learning intervention and use the findings iteratively. Therefore, HCPs in frontline oncology roles were identified, and their views sought on i) HCPs role in supporting families impacted by parental cancer, ii) content used in face-to-face educational intervention, iii) perceptions of e-learning interventions as an educational tool and iv) how best to promote engagement.

For this study, an initial focus group was conducted with an expert panels of HCPs (n = 16) who provided care to parents newly diagnosed with cancer (clinical nurse specialists (n = 7), psychologists (n = 2), social workers (n = 4) and counsellors (n = 3)). Predominately open-ended questions were used at the start of the focus group to explore views, beliefs and opinions on the role of HCPs in supporting parents newly diagnosed with cancer. More targeted and focused questions were used at the later part to test views on features that were acceptable and unacceptable when engaging with online learning. The focus group lasted approximately 40 min. Using thematic analysis, two themes were identified *'Getting started - equipping HCPs to* support *parents newly diagnosed with cancer'* and '*key user interface features to promote engagement with e-learning*'.

To facilitate this process of *'Getting started - equipping HCPs to* support *parents newly diagnosed with cancer'*, findings demonstrated that it was important that HCPs would be provided with an opportunity to reflect, contemplate and challenge core beliefs surrounding potential personal and professional barriers for them when communicating to parents about parental cancer. HCPs also identified the need to be equipped to manage difficult situations that may arise, such as parents not wanting to inform children about their cancer diagnosis. To aid learning, participants considered it important not only to integrate real-life examples of families impacted by parental cancer but provide age appropriate 'words' to describe cancer and its treatments to children,

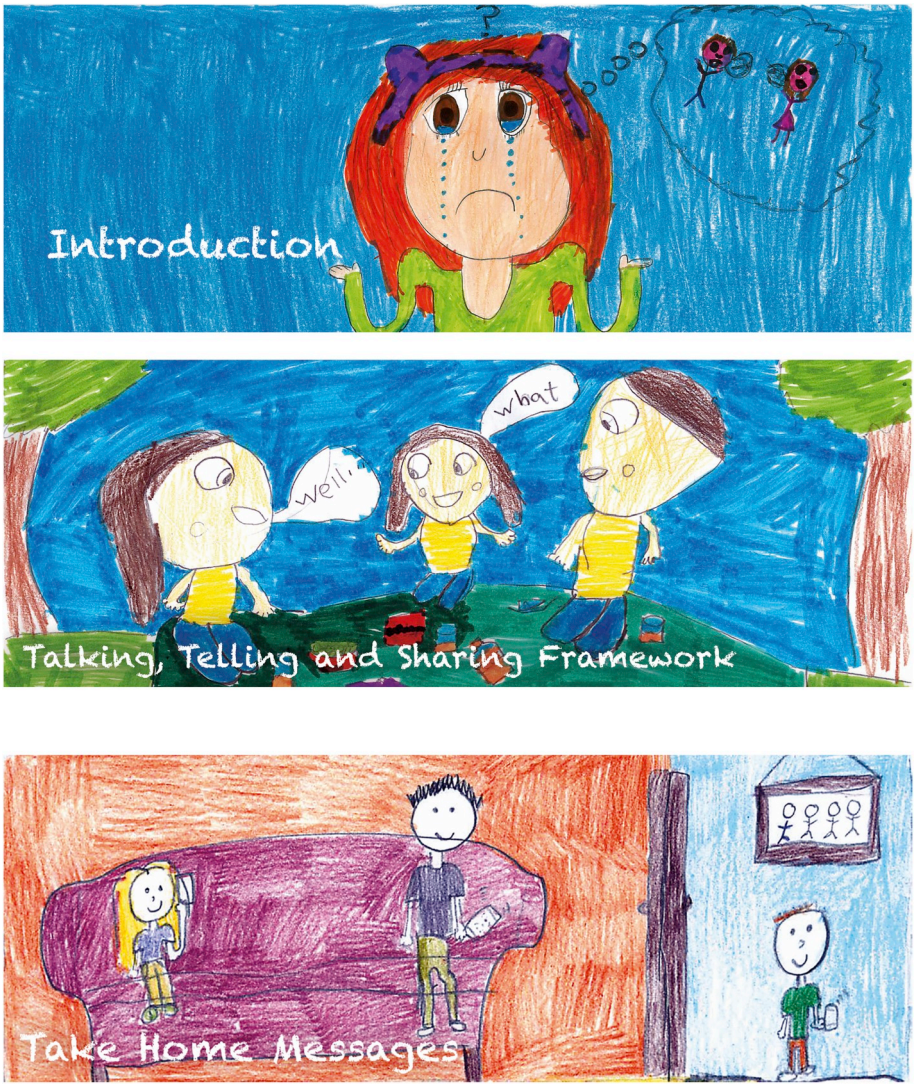

Fig. 2. Original artwork by children.

alongside an understanding of children's developmental responses and reactions to parental cancer. Finally, participants were keen to have a framework they could use in clinical practice to guide the conversation and cover the fundamental elements when talking to a child about their parents' cancer.

The *'key user interface features to promote engagement with e-learning'* reported were an interactive and engaging user experience, uncomplicated login and navigation, minimal but purposeful use of text. The findings from this focus group proved instrumental in the next step of this systematic process of producing the 'guiding principles', as reported in the following section.

4. Intervention design

4.1. Phase 3: Developing and refining the content for the e-learning module with the aid of a collaborative research group

A collaborative research group was established, to direct the development of a high quality, high impact e-learning intervention. This collaborative research group comprised of a Family Support Coordinator, Health Professionals working with cancer patients, researchers, parent with cancer, Learning Architect, E-learning designer and Video Director.

All sources of evidence from Phase 1 and 2 (i.e. review of the evidence and theory, qualitative study results) and expert opinion were brought together to formulate 'guiding principles'. The 'guiding principles' as outlined below stated the key intervention design objectives in terms of behaviour change and outcomes anticipated and the key features of the intervention required to achieve the objective.

The ***objective*** of the intervention was to develop an interactive e-learning intervention to enhance HCPs self-efficacy *(behaviour)* when supporting parents newly diagnosed with cancer to improve communication with their children *(outcome)*. The ***key features*** of this intervention were primarily extrapolated from focus group data. They were to:

- Provide a platform for HCPs to reflect on their beliefs and explore barriers when communicating with families about parental cancer
- Provide an evidence-based rationale for promoting open communication with children surrounding parental cancer
- Provide approaches to help integrate the e-learning content into routine clinical practice through the use of behaviour change techniques
- Provide a 'framework' to equip HCPs in routine clinical practice to empower parents with cancer to support and communicate with their children through the cancer diagnosis and treatment phase
- Provision of age appropriate language when communicating to children about cancer

- Minimal, yet purposeful use of text
- Engaging, interactive e-learning intervention using multimedia

Based on the evidence from the preparatory deductive and inductive work the subject experts developed an initial draft of the content. Through a collaborative approach with the Learning Architect, the initial content was honed and pedagogically revised, integrating the content with instructional techniques and media elements, which would facilitate and support the e-learning process.

This led to the development of a storyboard, illustrating how the information would be presented on each web page. Inherent in this systematic, rigorous and iterative process, qualitative research was employed once again to help further refine the content and develop the communication framework, through a focus group of frontline oncology staff (staff nurse (n = 1), clinical nurse specialists (n = 3) and social workers (n = 3)).

Following refinement of the storyboard, the E-learning Designer who had expertise in integrating media and interactive components, created the courseware for a learning platform. The authoring tool selected needed to be fully responsive to mobile devices such as tablets and phones, as this would aid flexibility of use, which was reported as an important prerequisite from the initial focus group (Phase 2).

The 'guiding principles' were reviewed and refined made by the subject experts. Modifications made at this juncture to facilitate intervention optimisation, can be reviewed in Table 1.

4.2. Phase 4: Usability testing of the e-learning intervention using think-aloud interviews

Aligned with the person-based approach, once the e-learning intervention was fully planned and a prototype version created, further qualitative research was essential to gain insight into its acceptability, usability and feasibility. For this step, the person-based approach advocates the use of think-aloud interviews, as part of an iterative process, moving between collecting participants' views, making changes to the e-learning intervention, followed by further testing to ascertain if the changes made are suitable (Yardley et al., 2015a).

The researcher (first author) introduced the concept of think-aloud interviews to participants, asking them to comment on whatever they thought and/or felt as they interfaced sequentially with each interactive screen page as it appeared ('tell me everything that passes through your head'). Participants were asked to comment specifically on functionality, content, navigation and format. It was re-emphasised at the commencement of the 'think aloud' interview that critical feedback would be particularly helpful. Throughout the interview, participants were prompted and probed to elaborate on any thoughts and feeling, especially when non-verbal cues were noted. There was no set time schedule for prompts; instead, they were raised as appropriate with each participant. This process also enabled the researcher to observe the interactive behaviour during use, which provided very detailed, immediate and observable reactions to every screen page. When participants reached the end of the e-learning module, a short semi-structured interviewed followed, which explored overall impressions of the e-learning intervention as an educational tool, usefulness to HCPs in clinical practice, the most important elements and how it could be improved. All verbal responses throughout the interview were digitally recorded and analysed thematically.

Three cycles of refinement with user retesting was performed from the first prototype build to the final product achieved, using 14 think-aloud interviews (see Fig. 3).

All fourteen participants, were recruited using purposeful sampling to ensure a range of health and social care professionals, working within the statutory sector (n = 7, two cancer nurse managers, two clinical nurse specialist, one social worker, one staff nurse, one oncology intern), voluntary sectors (n = 4, two social workers, one family support work and one art therapist) and the university setting (n = 3, cancer care researchers, two who were qualified nurses and one physiotherapist). The number of refinement cycles, therefore number of participants was not predetermined prior to commencement of data collection but saturation was based on no new concerns or meaningful modifications being identified.

Whilst the prompts were considered useful during the think aloud interviews, they did not constitute a large proportion of the data collected. The average duration of the interview was 55 min.

Analysis began after the first three interviews had been conducted and continued throughout data collection. It was obvious, following the first three interviews (cycle 1) that enhanced navigation was required, therefore, extra navigational tools were integrated into the design and these can be viewed in Table 2a. This modification was uncontroversial and essential even after one interview demonstrated by Participant 1, to

Table 1
Modifications made for intervention optimisation.

Guiding principles	Means	*RATIONALE*
• Provide a platform for HCPs to reflect on their beliefs and explore barriers when communicating with families about parental cancer • Provide approaches to help integrate the e-learning content into routine clinical practice through the use of behaviour change techniques • Provide an evidence-based rationale for promoting open communication with children surrounding parental cancer • Provision of age appropriate language when communicating to children about cancer	• Development of a series of short role-play videos demonstrating the dialogue between a parent and HCP on talking to children about parental cancer (role-modelling good practice to promote self-efficacy). Video clip 1) meeting resistance to share, 2) managing parental resistance to share and how to share, 3) reflection on sharing with children	Promote behaviour change following intervention mapping of behavioural determinants
• Provide a 'framework' to equip HCPs in routine clinical practice to empower parents with cancer to support and communicate with their children through the cancer diagnosis and treatment phase	• Further refinement of a step-by-step 'Talking, Telling and Sharing' framework to encourage HCPs to continue engaging with parents, when resistance is met through the addition of a dropdown box with a 'No' option leading to a subsection with 3 additional questions (persuasiveness, motivation, engagement).	Facilitate relatedness, motivation and maximise the impact of the message, consistent with 'guiding principles'
• Minimal, yet purposeful use of text • Engaging, interactive e-learning intervention using multimedia	• Incorporated original children's drawings of their perceptions surrounding parental cancer (see Fig. 2 for examples of children's drawing) Content reduction with paragraphs replaced by key statements. • Diagrams used to make the intervention more visually appealing. • Features that were not deemed essential were removed (e.g. superfluous messages).	Aid clarity, readability and acceptability

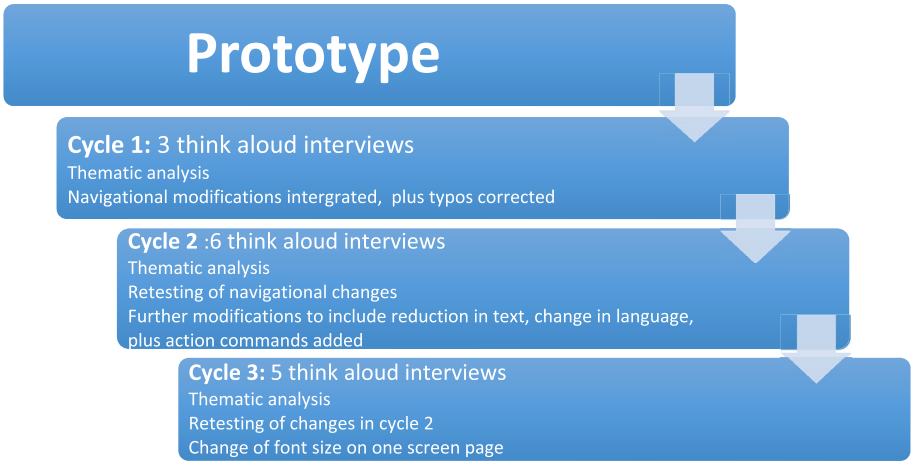

Fig. 3. Testing phase of intervention development using iterative think aloud interviews.

Table 2
Utilisation of data generated from 'think-aloud' interviews.

a) Navigational tools integrated into the e-learning design following cycle 1 of think-aloud interviews
- Indicator bar on each menu tile, to show progress through module.
- Scroll page indicator for progress in section, plus quick jump to topics.
- Functionality of menu icons made clearer and always visible.
- 'Next' and 'back' inserted into footer for navigation between sections.

•Interaction instructions made explicit, e.g. 'Submit' to 'View our feedback'ADD SPACE BETWEEN PARAGRAPHS seperating section a) and b)

b) Modifications made to the e-learning intervention based on feedback from 'think-aloud' interviews

CONTENT
- Reduction of statements from eight to six on two screen page
- Two typos corrected
- Text changed to increase acceptability for action commands for example 'Read transcript' was changed to 'Click here to read transcript' and 'submit' was changed to 'view our feedback'
- Change of language to increase acceptability on two occasions for example, 'It's important not to mislead or tell children 'half-truths'' to 'Children find dishonesty far more difficult to deal with'

VISIBILITY
- Integrated option to print PDF of 'Talking, telling and sharing framework' within section 2, as well as within resource section
- Increased font size of text, while reducing the size of the children's drawings within 'Children's developmental understanding'
- Re-positioning of two of the children's drawings to aid subject match.

enhance acceptability and engagement. *'As you move from the first page you have lost your sense of signposting and I'm not sure how long this module is as I don't know how many screen pages there are. Am I on page 2 out of how many?'* These navigational tools were tested during cycle 2 and proved both necessary and helpful, as highlighted in the following quote *'very simple navigation' by Participant 5*. In other instances, more data were collected to seek further views before implementing a change. These changes can be viewed in Table 2b, with findings reported under two themes: *'content' and 'visibility'*. Although these modifications could be considered as minor; nonetheless, they were adopted to impact effectiveness and feasibility. Furthermore, they were achievable within the resource and time allocation for the intervention development phase.

Following thematic analysis on all transcripts, four themes were noted. These were the '*appropriate use of children's drawings*, *'superior look and feel'*, *'value of the Talking, Telling and Sharing framework'* and *'pedagogical methods to improve impact'*. The analysis presented below focuses on these four themes.

'Appropriate use of children's drawings' – drawings conveyed children's perception of how parental cancer can impact a child, sharing key messages for e.g. how children are perceptive of change and often overhear adults discussing their parent's cancer diagnosis. Participants considered the use of these drawings as very effective and purposeful, which is evident from the following quotation '*brought it home to you at every step how important it is to focus and communicate with the children, who are at the heart of the family'*.

'Superior look and feel' – the screen pages were clear, visually appealing, not text heavy aided by some text disappearing when new information came to the forefront, drawings proved engaging, with consistent use of same background colour throughout. This 'superior look and feel' theme is demonstrated in the following quote. *'I like the consistent use of colour, the children's drawings are an excellent idea and using a video of you (nurse) in the clinical context is good and it brings it home that this is for frontline staff and people looking at the module can identify you as a nurse and allow people to see themselves as undertaking this role'*.

'Value of the Talking, Telling and Sharing framework' – for many this was the key component of the intervention that clinicians would use in routine clinical practice as highlighted by the following participant. *'this is very valuable, I really liked this. It gave me an algorithm and a sense of how to progress the conversation … this is the main thing I'm going to go away with. When a parent says I'm not ready to have the conversation then I have gentle, compassionate ways to encourage them to do so. That will really stay with me'*. Another participant reported that it gave her *'a very clear pathway and it gives me alternatives when I hit a road block in the conversation. If I had a parent in front of me tomorrow I would at least use some of these questions'*.

'Pedagogical methods to improve impact' – a range of interactive e-learning activities were embedded within the e-learning intervention, such as reflective components were users were asked to provide their views at key junctures. The following participant highlighted value in this learning exercise, reporting '*this is a good way to get people to think and engage. It is a good way to manipulate and use a programme, so you are doing some thinking and learning'*. Furthermore, the role-play videos were also reported positively as highlighted in the following quote '*hearing the words to use is very helpful, good way to role-model as the content is very good; very good for any healthcare professional'*.

Overall HCPs reported the e-learning intervention as a very useful and worthwhile educational tool, with immense relevance for the clinical area. The Cancer Conversation e-learning module is currently available free on Cancer Focus NI online learning platform (http://training.cancerfocusni.org). The next steps in this programme of work will focus on evaluating the e-learning intervention, which will employ a mixed methods approach to assess impact on self-efficacy of HCPs, user satisfaction and compare e-learning to traditional face-to-face training.

5. Discussion

In spite of the rapid growth in e-learning within healthcare, there is a death of literature explicitly providing theory-driven insights into intervention development. This methodology paper addresses the gap, by clearly illustrating the systematic use of the person-based approach, by identifying and detailing the steps taken to guide the planning, development and testing of an e-learning intervention for HCPs. This allows the reader to not only obtain insights into the clarity of our decision-making at key stages but also provides a comprehensive 'road map' for using an iterative primary research approach to intervention development. Providing details on the foundations that underpinned the development of this e-learning intervention, promotes transparency surrounding each phases, therefore aiding methodological rigour.

One might argue that the development of this e-learning intervention, which incorporated the systematic application of theory, current evidence, and user-testing is not unique to the person-based approach, as outlined by Yardley et al (2015a, b). It is clear that the Medical Research Council guidance outlines that the development of complex interventions should be systematically based on the latest evidence and be guided by appropriate theory (Medical Research Council Guidance, 2008). Others may propose that combining theory, evidence and user-testing are the core pillars to developing evidence-based healthcare (Khan et al., 2003) and again not unique to intervention development using this person-based approach.

The originators of the person-based approach (Yardley et al 2015a, b) would concur that theory-based approaches are vital and provide valuable frameworks to identify and change the determinants of behaviour. However, the person-based approach complements this by gaining an in-depth understanding of the perspective of the people who will use the intervention and the context the intervention will be used within (Band et al., 2017). While existing theory and previous research helped us anticipate many factors that would influence the development of the e-learning intervention such as incorporating real-life scenarios and use of language that is age-appropriate (Semple et al., 2017), it was through the application of the inductive elements of the person-based approach that vital insights were revealed. This not only provided a rich, in-depth understanding of the barriers (e.g. parental resistance) and facilitators (e.g. role play) to this specific intervention and user population but also the opportunity to incorporate salient elements into the prototype for testing. For example, identification of the need, and therefore subsequent development of a downloadable step-by-step framework to guide HCPs conversations with parents on telling their children about cancer, for use in routine clinical practice. Capturing and incorporating such evidence is key, to not only promote learning, but also increase the acceptability and hence likely engagement with, and effectiveness of the intervention.

A further distinguishing feature of the person-based approach from the MRC (2008) guidance on the development of complex interventions, is the use of think-aloud interviews for usability testing. In the field of human-computer interaction, usability testing is a vital step to ascertain the extent to which end users find an intervention easy and attractive to use (Pagliari, 2007). There are clear dimensions of convergence between the person-based approach and evaluating user's perspective on acceptability, engagement and satisfaction for online interventions. Although these are necessary and important points of consideration, the focus and goals for using think-aloud interviews in this study reach beyond mere satisfaction and user acceptability. A key focus was to ensure the e-learning intervention was effective to change behaviour, namely improve self-efficacy of HCPs when supporting parents diagnosed with cancer to communicate with their children. Therefore, when conducting think-aloud interviews it was essential that participant feedback extended beyond reactions to the 'look and feel' of the screen pages but views were elicited on the intervention content, for example, barriers encountered and opinions to promote engagement and confidence.

In reality, there is great diversity in how think-aloud interviews are performed as part of usability testing. This ranges from Ericsson and Simon (1984), who are generally considered as the originators of think-aloud interviews, advocating a very precise technique to include initial instructions on how to complete the intervention being tested, followed by the very general instructions, to 'think-aloud' and to 'verbalise everything that passes through your head'. As cognitive psychologist, Ericsson and Simon urge caution to interacting with participants after the simple, basic instruction is given as this may change the structure of the thought process itself. On the other hand, Cotton and Gresty (2006) describe a 'prompted think-aloud' interview, which provides the opportunity to intervene and engage with participants during period of silence with prompts such as with 'could you tell me why or how … ', instead of saying 'keep talking?'.

For the purposes of this study we used a prompted think-aloud approach, as our experience of using think-aloud interviews mirrors that of Milton and Lyons (2003) who reported that some participants find this task of 'thinking aloud' more challenging than others. For the participants who found these interviews more challenging, prompts were required by the researcher to get beyond a mere superficial commentary on what was aesthetically appealing. Using this prompted approach, we gained a wealth of rich and detailed information on the use of the intervention in real-time (both positive and negative), enabling changes to made such as navigational tools to optimise the intervention. It's important to note, rich data is not only provided through the verbalisation of users' thoughts as they interacted with the intervention but the think-loud interviews also provided an opportunity to observe the interacting, therefore determining the validity of the response through observation. This unique information gained from observation during task performance could not have been gleaned from questionnaires or focus groups data.

Some intervention developers omit this important phase of usability testing, viewing it as time consuming, expensive and labour intensive (Nørgaard and Hornbæk, 2006). On the contrary, we would argue that this is a necessary step, to avoid developing a product that has inherent flaws, leading to lack of engagement with the intervention, not achieving the behavioural change and desired impact with end-users. Instead, adequate time and development costs should be factored in at the early planning and funding phase of the project to enable usability testing to be conducted, as it likely that aspects of the intervention will need to be modified or 'fixed' before the release of the resource or product. As part of our project plan, adequate time and costings was mapped out for three cycles of refinement through think-aloud interviews, as illustrated in Fig. 3.

We elicited comprehensive feedback from users on the prototype through think-aloud interviews, which sometimes included differences of opinions and perspectives, one of the challenges was deciding what refinement or modifications should be made. As part of this iterative step, the following factors were used to help guide our team as to what modification should be made, which included: a) not removing features of the intervention that theory or evidence suggest may be critical to its success, and b) had to be in keeping with the guiding principles. Also, any recommendation to be acted upon, had to optimise the e-learning intervention to ensure it was acceptable, engaging and feasible, thus promoting engagement and ultimately effectiveness during implementation.

Subsequent to the development of this e-learning intervention, Bradbury et al. (2018) outlined helpful '*criteria for deciding whether to make modifications'* based on user feedback. They advocate that modifications should be made that are consistent with the 'guiding principles', important for behaviour change (e.g. acceptability, feasibility, persuasiveness, motivation, engagement), uncontroversial and easy to implement and repeated by several participants. Furthermore, modifications can be prioritised using the MoSCoW criteria (Must have, Should have, Could have, Would like) (see Table 3 for the '*MoSCoW criteria for prioritising which modifications to make'*). These authors

Table 3
Criteria for prioritising which modifications to make (MoSCoW).

Criteria for prioritising which modifications to make (MoSCoW)	
Must have	This modification must be made in order for the intervention to be effective in changing a participant's behaviour (given what we know about the evidence base).
Should have	This modification should be made if possible as it may impact effectiveness, but may be able to be delivered in a different way, or is in some way less critical than a Must have.
Could have	This modification would be useful, but may be less critical to behaviour change than a 'should have' and may only be implemented if time and resources are available.
Would like	This modification is not needed to support behaviour change, but could be useful if time and resources allow.

suggest that it is sometimes obvious that a potential change is a high priority, even after only one think-aloud interview, like our navigational difficulties, whereas, in other cases more opinions are required before implementation of a change. On reflection, the fundamental premises of what Bradbury et al. (2018) describes as *a 'novel, efficient approach to analysis and criteria for deciding when to implement intervention modifications'*, is consistent with the approach our team adopted which is reassuring. For example, a 'Must have' was developing the communication framework, and our 'Should have' was the development of videos modelling good practice.

It's important to raise one area of potential concern with this criteria, recently published by Bradbury et al. (2018). It is specifically with the criteria labelled as 'uncontroversial and easy to implement'. Caution must be given to considering modifying an intervention because an aspect or item is solely easy to implement. Although it might be easy to modify, it doesn't necessary mean it will be helpful. Conversely, something that is initially considered controversial may prove, with further exploration and analysis, integral to the success of a product under design. Furthermore, to help manage any potential 'tensions' that may present as result of differing opinions and viewpoints expressed during 'think-aloud' interviews and, or reducing the potential for 'bias' of the interviewer to adopt modifications it is fundamental that as part of each refinement cycle the expert group is consulted and agreement reached through a consensus process.

6. Limitations

Although, there is much agreement amongst the seminal researchers of the person-based approach that inductive studies are particularly valuable at the intervention planning stage, to provide important information about which intervention features might be acceptable (or unacceptable) to the target population (Yardley et al., 2015b; Bradbury et al., 2014). The limitation of using this approach in intervention development is that the small samples employed might not be representative of the entire target population and some viewpoints may therefore be missed. However, to minimise the impact of this, purposeful sampling approach was used, identifying a wide range of professional bodies such as staff nurses, clinical nurse specialist, social workers, psychologist, and counsellors with a variation in age and years of experience working in cancer care were recruited throughout.

A further limitation of this study was that think-aloud interviews were conducted by a researcher who was involved in the development of the e-learning intervention, which might have influenced or positively biased the findings. Nonetheless, this seems less likely, due to a myriad of positive and negative views expressed.

7. Conclusion

This methodology paper has sought to clearly outline the steps taken, guided by the person-based approach, to develop an empirically derived e-learning intervention. It presents a systematic approach to intervention planning, developing and testing of an e-learning intervention with HCPs as target users. We showed how current evidence, theory and qualitative data was used inductively and iteratively to inform intervention development. This should help inform and guide other intervention developers. During usability testing, a number of modifications were made based on user feedback from think-aloud interviews. Decision-making surrounding what user perspectives to adopt during this phase, should be centred on the guiding principles and in keeping with evidence and theory to promote effective behavioural change.

Having adopted the person-based approach it is hoped that this e-learning intervention is not only acceptable and engaging but will be an effective intervention to increase HCPs awareness and self-efficacy when communicate with parents impacted by parental cancer. The next step is formally conducting an evaluation of the e-learning intervention.

Conflicts of interest

Both authors above have no competing interest and have no conflicts of interest in regards to the research described in this submission. We would like to acknowledge funding from the HSC R&D Division Northern Ireland.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejon.2019.05.006.

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