

## Development of the 'ACT now & check-it-out' intervention to support patient-initiated follow up for Head and Neck cancer patients

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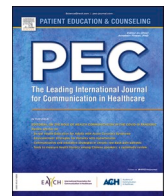
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## Patient Education and Counseling

journal homepage: [www.journals.elsevier.com/patient-education-and-counseling](http://www.journals.elsevier.com/patient-education-and-counseling)Development of the ‘ACT now & check-it-out’ intervention to support patient-initiated follow up for Head and Neck cancer patients<sup>☆☆☆</sup>

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## ABSTRACT

**Objective:** Current Head and Neck cancer (HNC) follow-up models are considered sub-optimal at detecting recurrences. We describe the development of a patient-initiated follow up (PIFU) trial intervention support package, to support HNC patients to engage in PIFU self-care behaviors.

**Methods:** An intervention mapping approach, informed by evidence synthesis, theory and stakeholder consultation, guided intervention development. Data sources included a patient survey (n = 144), patient interviews (n = 30), 7 workshops with patients (n = 25) and caregivers (n = 3) and 5 workshops with health professionals (n = 21).

**Results:** The intervention (‘ACT now & check-it-out’) comprises an education and support session with a health professional and an app and/or a booklet for patients. The main targets for change in patient self-care behaviors

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were: assessing what is normal for them; regularly checking for symptom changes; prompt help-seeking for persistent/new symptoms; self-management of fear of recurrence; engaging with the intervention over time.

**Conclusions:** We have developed an evidence, person and theory-based intervention to support PIFU self-care behaviors in HNC patients.

**Practice implications:** A trial is underway to assess the effectiveness and cost-effectiveness of the intervention. If successful, this intervention could be adapted for patients with other cancers or diseases, which is important given the recent shift towards PIFU pathways.

## 1. Introduction

Every year, approximately 1.5 million people worldwide are diagnosed with Head and Neck cancer (HNC) which includes cancers of the oral cavity, pharynx, larynx, sinuses and salivary glands [1,2]. HNC is the 8th most common cancer in the United Kingdom (UK), affecting around 12,400 people each year, and incidence rates have risen by around a third since the 1990's [3]. HNC and its treatment can result in significant deterioration in quality of life, due to loss of function in the ability to eat, swallow, speak, taste and smell, as well as psychosocial impacts including distress over body image, disfigurement, fear of cancer recurrence, and major depressive and anxiety disorders [4–10]. Subsequently, HNC has one of the highest disease burdens of any cancer type [11]. There is also an emotional burden on caregivers who display considerable psychological and social support needs [12].

Currently in the UK, follow-up care in HNC is typically consultant-led and hospital based, involving intensively scheduled appointments every few months for up to five years post treatment. It has been suggested that the current follow-up models may be sub-optimal at detecting HNC recurrences, as these are more often detected by patients between routine hospital visits [13]. Increasing demands placed on cancer follow-up services have led policymakers to call for risk-stratified follow-up models [14]. Patients and health professionals have also expressed dissatisfaction with the current model of follow-up [15,16]. Patient-initiated follow up (PIFU), whereby patients take responsibility for triggering their hospital follow-up appointments, is now a key priority of the National Health Service (NHS) in the UK [17,18]. Evidence to date for PIFU models has shown promising findings in other cancers and diseases, although there is a need for more research, particularly higher quality, larger randomized controlled trials in the future [19]. Health professionals working with HNC patients have expressed enthusiasm for PIFU models, although concerns remain about potential harms for more disengaged or more anxious patients [16].

Due to the lack of existing research on PIFU in HNC and the rising numbers of HNC patients [20,21], the PETNECK2 research programme was developed with six workstreams (National Institute for Health Research programme grant for applied Research NIHR200861 [22]). The planned PETNECK2 randomized controlled trial (RCT) aims to compare PET CT-guided, symptom-based, patient-initiated follow-up with current routine surveillance for HNC patients in terms of overall survival and cost-effectiveness. Patients in the intervention arm will receive a Positron Emission Tomography (PET) combined with computed tomography (CT) (PET CT) scan at around one-year post treatment which will identify those at low risk of recurrence [23]. Instead of regularly scheduled follow-up appointments, patients randomized to PIFU will be responsible for monitoring any symptom changes and triggering further hospital appointments themselves. In order to support patients on PIFU, we developed an intervention package to give patients information and support regarding checking and monitoring symptoms of possible recurrence and regarding seeking help for any concerns in a timely manner. This paper describes the development of the intervention support package.

## 2. Methods

Intervention development was one of six workstreams of the

PETNECK 2 programme grant. The wider multidisciplinary study team met monthly- the Programme Management Group (PMG) which was to oversee the entirety of the project. Specialists in intervention development within the PMG formed a separate intervention development (ID) group (comprising all authors), who met independently and discussed each step of intervention development, including the content and delivery of the intervention.

### 2.1. Design

We used digital intervention development techniques from the Person-Based Approach [24], alongside a systematic framework for intervention development, intervention mapping [25,26] to develop an intervention package to support HNC patients on PIFU one-year post treatment. These methods ensured that the support package was evidence-based, informed by behavior change theory (COM-B model) [27], and person-centered [24,28,29]. The approach to intervention development included the following initial four steps, which were iterative, not linear [25,26]:

- 1) identifying targets for behaviour change and patient support needs;
- 2) identifying the determinants of change and integration of needs assessment data;
- 3) specification of change techniques and strategies to match the above determinants;
- 4) production of digital app and booklet intervention (patients) and training materials (health professionals).

The intervention development process synthesized data from different sources (Fig. 1) at different timepoints (Fig. 2).

The study was approved by North East-Tyne & Wear South Research Ethics Committee, the Health Research Authority and Health and Care Research Wales, reference [20]/NE/0102. All participants provided informed consent.

#### 2.1.1. Patient Advisory Group (PAG) workstream

The intervention development process involved detailed input and involvement of a Patient Advisory Group (PAG) which convened monthly. The PAG were formed at the study inception and had their own workstream in the programme grant. They provided input in all of the other workstreams. The group consisted of nine members including one caregiver, with a range of professional backgrounds and types of HNC diagnoses. Two PAG members (DS, PR) attended PMG and ID group meetings to provide ongoing input, and are authors on this manuscript. Members were involved by advising on patient documentation, providing input on the intervention and its iterations (e.g., content, features and layout of the app and booklet, education and support session) and usability testing. Online PAG discussions took place throughout the data collection phase focusing on the content of the app and booklet, behavioral determinants, the intervention prototype, and the education and support session.

#### 2.2. Identifying targets for behavior change, patient support needs and behavioral determinants - Steps 1 and 2

Step 1 involved gathering information on views towards PIFU and on

patient-related facilitators and barriers to adherence to PIFU, patient support needs and identifying the targets for behavior change. Step 2 involved identifying the behavioral determinants of change and the integration of needs assessment data. Steps 1 and 2 informed the development of the intervention support package (both the app/booklet in addition to the content of the education and support session, and health professional training package) and were iterative, rather than sequential steps in the intervention mapping process. The methods used are outlined below:

2.2.1. Evidence reviews

A systematic review was conducted (studies up to January 2022) to identify key patient facilitators and barriers relating to PIFU in treated cancer patients of any diagnosis. Full findings of this systematic review are reported elsewhere [30]. The systematic review workstream updated the ID team on the included studies to date around March 2021 (giving further updates as the search was updated) to inform the development of the intervention as it evolved. A scoping review of non-academic literature (relevant online educational and support resources provided by the NHS and UK cancer charities for HNC patients) was also conducted (between October 2020-March 2021). This found a dearth of existing patient information on support and information for long-term HNC survivorship, apart from one resource from the UK-based cancer charity Macmillan [31]. Therefore, patient information and materials (including existing apps) for breast, skin and testicular cancer regarding self-examination were reviewed, which provided useful information (key messaging, app features, language employed). Only one UK film clip regarding HNC self-examination aimed at patients was included in the final resource (The Mouth Cancer Foundation). Existing up-to-date patient online resources for managing anxiety, general support and lifestyle behaviors were identified during the app development phase, guided by input from participants and PAG members.

2.2.2. Behavior change framework and underpinning theory

The COM-B model theoretical framework [27] and the Behavior Change Techniques Taxonomy [32] were selected a priori to develop a clear specification of the target behaviors, understand the enablers and barriers for the behaviors (e.g. patient confidence regarding checking for symptoms), and identify intervention techniques to modify the enablers and barriers to behaviors, thus informing the design of the intervention resource. The COM-B [27] framework also informed the topic guides for

qualitative data collection and the survey.

Self Determination Theory (SDT) [33] was also selected a priori as a framework to embellish the “Motivation” component of the COM-B model and to guide the delivery of the patient education session, health professional training elements and applied to the app content. This theory emphasizes the beneficial impacts of more self-determined motivation for behavioral engagement (i.e. engaging in the behavior for more autonomous reasons). SDT also holds that self-determined motivation will be promoted if patients’ needs for autonomy, competence (efficacy) and relatedness are supported via the intervention. In particular, the concept of autonomy-support within SDT is reflected in consideration of the patient’s perspective, giving choice, the provision of meaningful rationales, and avoidance of the use of controlling language (‘must’, ‘have to’ and ‘should’). Our stakeholders felt that the support of autonomous reasons for engagement in the intervention (and use of autonomy supportive strategies) was appropriate (i.e. reflects a more sensitive and patient-centred communication style) and necessary to support patients to learn to self-manage a complex and potentially anxiety-provoking situation.

2.2.3. Stakeholder consultation

We conducted interviews and workshops with patients, their caregivers, and with health professionals, and distributed an online survey to patients to identify areas of need surrounding PIFU and targets for change. Patients were recruited by members of their clinical team (consultant or nurse) at participating NHS hospitals or through HNC support groups and organizations (e.g., The Swallows, Heads2together, Northern Head and Neck Cancer Charity). Patients were given a participant information sheet and asked to complete a consent form. Eligible patients were over 18 years old and previously treated for HNC within 5 years (interviews and workshops only, no time limit for survey). Patients’ family and friends could participate as caregivers. Patients were excluded if they had recurrent or metastatic disease, were undergoing treatment for other cancers, or lacked capacity to give informed consent. Patients were invited to participate in any or all of the three options (interview, workshop, survey).

Interviews were conducted with patients either online (via Microsoft Teams) or by telephone and all workshops were conducted virtually via Zoom due to the COVID-19 pandemic. Workshops and interviews were all conducted by experienced qualitative researchers (JB, LM, AL, MJ) with applied health, not clinical, backgrounds. Semi-structured

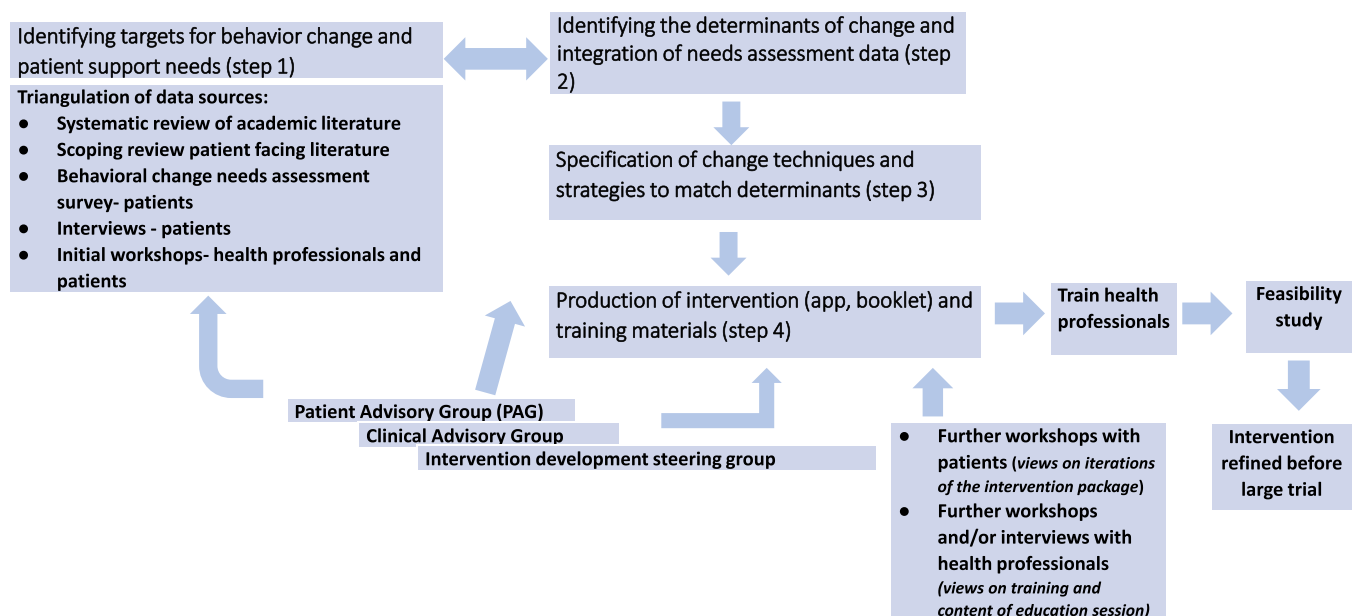


Fig. 1. The Intervention Development Process.

interviews were conducted by AL/MJ between November 2020 and February 2021, and lasted 30–60 min approximately. Family members were interviewed simultaneously or in separate interviews, depending on patient preference. Interviews covered views about PIFU and views on the content of the intervention [34].

Health professionals were recruited for participation in online workshops through previous focus groups conducted for the PETNECK2 study, as reported previously [16], and through mailing lists of professional bodies. Those who expressed an interest in participating in the workshops were recruited via email invitation. Three online workshops were conducted by JB/LM with a mix of health professionals including surgeons, oncologists, nurses and allied health professionals (AHPs) (e.g., speech and language therapists, radiographers, dieticians) involved in HNC patient care. Workshops explored views towards patient barriers to PIFU and the content of the app and the education and support session and lasted approximately 90 min.

Seven online workshops with HNC patients and caregivers were conducted in total. Patient workshops 1 & 2 (and health professional workshops) were conducted in January-February 2021. Patient workshops aimed to elicit views on the barriers and facilitators of the target behaviors, views towards the content and format of the intervention package (app storyboard and education and support session). The format of the workshops used elements of the Health Service co-design tool kit (such as inviting participants to reflect on a list of suggestions and to suggest improvements, brainstorming etc.) [35]. Workshops involved an initial presentation of the PETNECK2 study design, followed by a presentation of the initial intervention aims and ideas by the facilitators (JB, LM) to stimulate group discussion. This was followed by a brainstorm to elicit further ideas and discussion. Ideas initially presented at workshops 1 and 2 were informed by the evidence reviews, and discussions with the PAG and PMG. Workshops 3–7 are described in step 4, and were conducted between May-July 2021.

2.2.4. Survey questionnaire

A survey was designed (Supplementary file 1), informed by the ongoing systematic review, discussions with the Patient Advisory Group (PAG) and constructs embedded in the COM-B behavior change model [27], to identify the most common barriers to and enablers of the target behaviors. It included questions on: *capability* (e.g., relating to knowledge; skills; confidence in relation to PIFU), *opportunity* (e.g., accessibility of reporting symptoms) and *motivation* (e.g., beliefs; fear of cancer recurrence). Additional "intervention scaffolding" [36] questions were included to identify patient preferences regarding intervention options

(e.g., mode of intervention; frequency of contacts with healthcare professionals). The survey also included questions regarding demographics, self-examination behaviors, views towards PIFU and the intervention content, needs and views towards family/friends' involvement. The survey comprised 36 questions in total. Some questions were open ended/qualitative. The survey was piloted with and refined by the PAG group. Participants completed the survey online or were given/posted a paper copy if requested [34]. The survey data were collected between November 2020 and June 2021.

2.2.5. Analysis

Interviews and workshops were audio-recorded, transcribed verbatim and analyzed using thematic analysis [37]. AL/MJ conducted the analysis of patient interviews, and LM/JB analyzed workshop and health professional interview data. NVivo software was used to manage the data analysis. A framework matrix in NVivo was developed that included both inductive and deductive themes from the workshops. Deductive and inductive concepts were developed to allow for inclusion of existing theory in the development of themes, as well as themes that emerged from participants accounts. A separate framework was developed for both health professional and patient workshops. Survey data were analyzed using descriptive statistics and simple categorization of open-ended responses. Full patient interview and survey findings are reported in detail elsewhere [34]. Demographic information of workshop participants is presented in electronic Supplementary file 2 (information regarding socioeconomic status was not collected).

2.2.6. Data triangulation

An intervention mapping approach, informed by evidence synthesis, theory and stakeholder consultation, guided intervention development. Following analysis of data sources including the patient survey, patient interviews, workshops with patients and caregivers and health professionals as well as the systematic review and PAG discussions, the data sources were triangulated [38]. A table of the key findings from each data source was created, with a row for each of the deductive (including COM-B elements) and inductive concepts and a column for each data source. Key findings such as barriers and enablers to change, as well as views towards the intervention content, were thematically grouped within the rows of the table, and then findings from each source were examined to see where they converged, offered complementary information or diverged. Divergence was discussed at team meetings, with the PAG, and at patient workshops. For example, inclusion of resources on healthy living were not viewed as a priority for some patients, but



Fig. 2. Timelines for Intervention Development.



were deemed beneficial by health professionals and the PMG to include in the intervention [39]. The table in electronic Supplementary file 3 highlights a simplified version of this initial table, with a cross (x) indicating whether each theme was present. Themes identified in the synthesis were organized into a logic model [40] for the intervention.

### 2.3. Specification of change techniques and strategies- Step 3

Targets for change were identified from the data sources (see electronic Supplementary file 4) and presented in our results section. A behavior change technique taxonomy [32] was used to identify appropriate strategies for supporting behavior change that mapped onto and addressed the determinants (barriers and enablers) of change identified in Step 2. The strategies selected were informed by evidence, expert knowledge, data collected from multiple data sources and PAG feedback (see electronic Supplementary file 4).

### 2.4. Production of detailed intervention and training materials- Step 4

#### 2.4.1. Development of the prototype resources – mobile and web app

The GUIDED [41] and TIDieR [42] checklists were used in reporting the intervention content. Our synthesis of the above data, as well as information gleaned via health professional (1–3) and patient (1–2) workshops (January–February 2021), informed the storyboard for our app. This was then presented and discussed at meetings with the PMG and PAG and was emailed to the Clinical Advisory Group (CAG), which included clinicians, nurses and AHPs who were invited to comment. App development by a professional app company then commenced. The prototype resource was presented at further patient workshops (3–4, conducted in May 2021) to elicit views regarding the format, content and delivery of information and support. An acronym for PIFU self-care behaviors was developed for the prototype resource through discussions with PAG members and the PMG. One PAG member (DS) suggested the acronym initially and the exact wording was then further developed by team discussions. The resource was revised and re-presented at further patient workshops (5–7, conducted in July 2021). A few participants (n = 5) had already participated in earlier workshops but most had not. Participants in workshops 5–7 downloaded the app a week before the workshop. If participants were unable to attend workshops, a few provided email feedback on the prototype resource. A usability-testing workshop [24,28] was conducted with the PAG, in addition to several external users (n = 5) who had not previously seen the app, who were asked to complete set tasks to test usability and ensure ease of use of the prototype app. The app was also downloaded by members of the CAG, PAG and PMG who provided feedback. The app underwent minor revisions following usability testing. Readability of the resource (reading age 11 or below) was determined using the Flesch–Kincaid Grade Level [43] and Simplified Measure of Gobbledygook (SMOG) grade [44] which deemed it suitable for the UK and in patient friendly language.

For inclusion in the app and website, an animation film was developed. Firstly, a script was developed by the research team with iterative input from the PAG members and the wider PMG. Several iterations were developed and ongoing feedback was incorporated into the final version, which was produced by a professional illustrator.

#### 2.4.2. Booklet

A paper-based booklet version was developed, which included content identical to the app, with some minor modifications. The format was discussed during patient and PAG workshops. Using the same methods, some new and some existing participants were recruited to comment on the prototype booklet. Feedback was requested from 15 patients. Some of these patients described themselves as having low digital literacy or not being comfortable with using apps or smartphones. A few provided feedback over the telephone (n = 3), most preferred to email their feedback (n = 10) and 2 did not respond.

#### 2.4.3. The education and support session and Health professional training package

Patients' views towards the content of the education and support session (a face-to-face appointment with a health professional as part of the intervention package), were collected during workshops 1–4, and this was also discussed with PAG members. In addition, further data collection was carried out in order to gather health professional views towards the content of the education and support session, their training needs as well as the format, content and delivery of the training package for staff delivering the session. Therefore, two further online workshops (workshops 4 and 5) were conducted with nurses and AHPs (n = 6) as well as one online interview (n = 1) to discuss their views.

#### 2.4.4. Design

The education and support session was designed to be flexible to individual needs, to allow patients to discuss any concerns or barriers to PIFU or the target behaviors, using person-centered counselling techniques, including motivational interviewing [45,46]. These techniques aim to enhance the patient's autonomy for changing their behavior, and include empathy-building skills, reflective listening, and a collaborative/shared decision-making style. This method of delivery means that health professionals will provide tailored support or advice, whilst the patient also receives standardized information and support through the app/booklet resource.

Following consultation with health professionals on their training needs, in addition to frequent discussions with experts in our ID group and the wider PMG group to review content and materials, a training package was developed for nurses and allied health professionals. Psychologists with expertise in fear of recurrence (GO) and behavior change/motivation (CG, JD) compiled the content of individual modules. A 'typical' education and support session was filmed by MW and two PAG members to provide an exemplar consultation, which was divided into 6 short film clips.

## 3. Results

### 3.1. Targets for change

Our synthesis of the data, which was an iterative process incorporating data collection and PAG input from across steps 1–4, identified five key objectives of the intervention package:

1. To support patients to recognize potential symptoms of HNC recurrence, by identifying what is "normal for me" and possible deviations from this normal.
2. To support patients to routinely check for potential recurrence symptoms.
3. To facilitate timely help seeking by patients, making a hospital PIFU appointment if needed.
4. To minimize and help patients to self-manage fear of recurrence.
5. To encourage patients to continue to engage with the above self-care behaviors and the intervention over time.

A secondary intervention target identified was:

6. To support patients to self-manage any treatment related side effects and to seek help in a timely manner for such concerns.

(N.B. Target 4, managing fear of recurrence can be seen as both a target for change and as a determinant of other self-care behaviors. Target 6 was not an initial target for the intervention, but came out through the stakeholder consultation as a secondary target, to ensure that the patient's usual care pathway (i.e., access to allied health professionals if required) is replicated while on PIFU).

### 3.2. Logic Model

A logic model of the intervention is presented in Fig. 3, highlighting

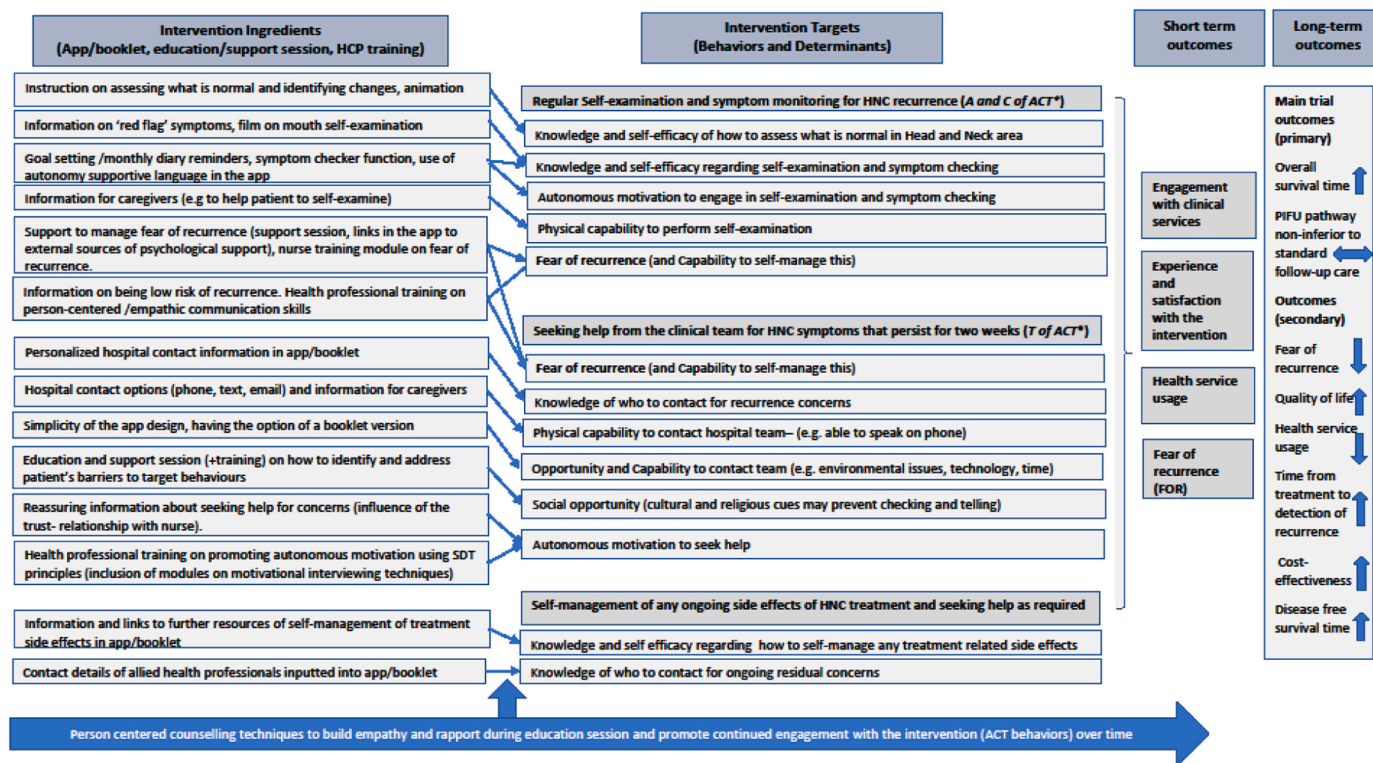


Fig. 3. Logic model of the intervention.

the intervention outcomes, intervention ingredients and the short- and long-term outcomes of the intervention.

### 3.3. Key features of the intervention package

Following the synthesis of data from steps 1–4, Table 1 presents the key features of the intervention that were included in the app and booklet resource, the barriers or facilitators to behavior change and targets to behavior change they address.

#### 3.3.1. Content of app/booklet

Table 2 provides an overview of the content of the PETNECK2 app and booklet (see the PETNECK2 website for further information – www.petneck2.com). The ACT acronym developed aimed to portray the key messages regarding the target self-care behaviors required on PIFU. The ACT acronym stands for:

- A- Assess and be Aware of what’s normal for you.
- C- Check for Changes regularly.
- T- Tell your hospital Team about any concerns you have.

The phrase ‘ACT now and check-it-out’ was repeated throughout the app/booklet and is the name of the intervention.

#### 3.3.2. Animation

An animated film developed for patients to view in the app aimed to demonstrate, instruct and model the ACT behaviors, which were key behavior change techniques [32]. Screenshots of the final animation film are in electronic Supplementary file 5.

#### 3.3.3. The education and support session

The education and support session (Table 6 electronic supplementary file) aims to promote autonomous motivation in patients regarding the target behaviors and to overcome any barriers to PIFU. The session is a one-off, one-to-one, approximately 30-minute session (face-to-face at the hospital), with a clinical nurse specialist/AHP or research nurse (depending on availability).

Timelines for patients randomized onto the PETNECK2 intervention arm are as follows:

- PET-CT scan (approximately one-year post treatment) to establish low risk of cancer recurrence, followed by a consultation to discuss results.
- Patient given information on how to download the app.
- Patients have a 30-minute education and support session with a nurse/AHP.

Patients will have access to an ‘open urgent’ PIFU appointment to see their hospital team within 2 weeks. An ‘open urgent’ appointment allows patients to contact their hospital team if they have any concerns while on PIFU, and they are guaranteed to wait not longer than 2 weeks. This replaces their regular hospital follow up appointments.

#### 3.3.4. Nurse/allied health professional training package

Electronic supplementary file 7 provides an overview of the content of the training package for intervention delivery personnel (HNC clinical nurse specialists, AHPs or research nurses), which lasts approximately 2.5 h in total. The training package was delivered remotely through an online platform (Learning Hub- an NHS accessible site), so health professionals could watch and re-watch modules at a convenient time. To promote reflection on training content, several multiple-choice questions were asked after each module. Virtual discussion forums were offered to health professionals taking part in the PET-NECK2 trial to discuss any ongoing issues with delivering the education and support session.

## 4. Discussion and conclusion

### 4.1. Discussion

We designed the ‘ACT now & check-it-out’ intervention to address the key needs of PIFU patients. Using an evidence-, theory- and person-

**Table 1**  
Key intervention features.

Key intervention features	Barriers or facilitators to behavioral change (COM-B and SDT elements)	Targets for Change	Exemplar quotations - patients
Simplicity and ease of use	Speech or language barriers (e.g. non-English speakers) (Physical capability)	2,3,5	"Keep it fairly simple, all these other things you mention are useful but not at the forefront of the App"
Focus on the key behaviors (ACT message) – with separate additional information	Beliefs regarding the importance/significance of symptoms (delay) or help-seeking behaviors (autonomous motivation to perform target behaviors and psychological capability)	1,2,3	"For me the clarity and simplicity of working out if you need to see a doctor or not is the most important thing and then all of the additional information but very clearly separate."
Information on knowing what is normal and checking for changes to their normal and symptoms of recurrence	Knowledge regarding symptoms of recurrence. Lack of understanding of the importance of recognizing and reporting symptoms (psychological capability-knowledge); Self-efficacy towards detection of symptoms/self-examination (psychological capability-skills)	1,2	"It is change I think, that is the single most important thing, anything that is different from the last time you looked in"
Film(s) to demonstrate how to check for symptoms of recurrence	Barriers to self-examination – difficulties of physically examining themselves or knowing what is normal (physical capability); Self-efficacy towards detection of symptoms/self-examination (psychological capability-skills)	1, 2	"One of the things I would find useful is someone to show me how to examine myself. Also look at the video together but then have the nurse show me."
Reminders/prompts for self-examination and checking for symptoms of recurrence	Habits surrounding self-examination/checking for symptoms (Habit formation); Prompts to target behaviors e.g. reminders to check for symptoms and to call helpline (Physical opportunity)	2, 5	"To have a reminder on an app, that makes you do it once a month, once a fortnight, I don't know, so you get into a habit of doing it, you know, that would be a good thing."
Symptom recording function – different options to suit individual preferences	Prompts to target behaviors e.g. reminders to check for symptoms (Physical opportunity to perform target behaviors)	1,2,5	"If you have a [symptom] diary you can look back and see if you have spotted that same symptom in the past and if it is something that occurs infrequently that will help to reassure you. But if it is something new you would then be aware to get that investigated."
Non-digital options	People with low literacy (including technical literacy) and low language literacy (Physical capability)	5	"You've got to think about people who don't have online access. .... Also, you've got people where English isn't their first language. .... So how can this be created so it is equal for everybody."
Ensure quick, reliable and easy access to the hospital team	Knowledge regarding how to and the process of seeking help (psychological capability- knowledge); Self-efficacy about seeking help (psychological capability-skills)	3, 6	"On the app, have a 'contact us' little box, where you click and it automatically brings the e-mail address for whoever the point of contact is, or a phone number"
Provide reassurance over seeking help from the hospital – (including allied health professionals if needed, in order to replicate usual care pathway)	Missing the reassurance of regular visits and perceived access to allied health professionals – a barrier to acceptance of PIFU pathway	6	"It needs to be part of it, so you go and see your mental health specialist as well as going to see the dietician and the speech therapist just to check in to see how you're getting on really."
Support with self-management of fear of recurrence and general wellbeing	Underlying fear of cancer recurrence (FCR) or anxiety/psychological issues	4, 5	"Remind people not only at the end but also at the beginning – calm them down and say 'have a look at this, work through this but bear in mind when you have got to the bottom of it and if it's not right then you can get an open urgent appointment'."
A section for caregivers	Caregivers as prompts to perform target behaviors (Social opportunity)	1,2,3,4,5,6	"He's [my husband] always felt my neck, since treatment. He's watched the consultant do it stood at the back, and then he knows how my neck feels, and occasionally he'll go 'ooh, that feels a bit hard', or 'ooh, that doesn't feel right'."
Peer support- links to patient forums and HNC organizations	Peer support as prompts to perform target behaviors (Social opportunity)	1,2,3,4,5,6	"we could perhaps discuss it in a group chat [with other HNC patients], like we are now."
Information on PIFU to highlight benefits to the patient	Beliefs surrounding PIFU (perceived as a cost saving exercise)	5	PAG meeting notes- it is important that patients do not perceive PIFU as a cost-saving exercise, and are aware of the benefits to the patient.

based approach, we triangulated data from multiple sources, ensuring that the views of intervention users and stakeholders were incorporated in the design. It is hoped that this will maximize the potential for the intervention to be effective, engaging, acceptable and useful to users [24,28]. This is important as care providers for most cancers and many other disease groups are considering switching to PIFU pathways [18], yet there is a dearth of a) intervention support packages for PIFU patients [47] and b) evidence on the effects of PIFU pathways on patient outcomes [48]. Patient resources and individually tailored support are required on this pathway, as existing qualitative research has shown that breast cancer patients already on PIFU pathways experience uncertainty over recognizing and reporting signs of recurrence [47].

Critical in the co-design of this intervention has been the close involvement of a dynamic and engaged patient advisory group (PAG), engagement of other stakeholders, and input from a multidisciplinary team of experts. Regular monthly PAG meetings with researchers present allowed for ongoing feedback and input, ensuring that the

intervention design was patient-centered. The wide range of expertise from PAG members provided excellent critical feedback on a range of aspects, e.g. patient-friendly language, usability and accessibility of the app/booklet and acceptability of patient-facing documents. Positive impacts of patient and public involvement (PPI) have been demonstrated in all stages of the research project cycle, whereby PPI has been shown to enhance the quality of research, such as enhancing the implementation and dissemination of findings [49]. However, challenges in engaging with multiple stakeholders included incorporating divergent views between patients and academics/clinicians, in which case the patient view was generally prioritized.

Limitations of our intervention development process included difficulties in recruiting an ethnically diverse sample - very few non-white patients participated in interviews (n = 1) or workshops (n = 2). We also did not assess socio-economic status of patients, or ethnicity in the survey. Future research needs to explore the views of seldom heard groups (e.g. minority ethnic groups) regarding PIFU and any specific



**Table 2**  
Overview of the ‘ACT now & check-it-out’ intervention- app/booklet.

Key elements	Content
Front page with icons	<ul style="list-style-type: none"> <li>• ACT acronym with icons for each letter</li> <li>• A ‘contact the hospital’ green button (with patients’ personalized contact details inputted for direct and easy access)</li> <li>• Icons to each of the key sections on the bottom of the page (‘patient-led follow up’, ‘set reminder’, ‘record symptoms’ and ‘support resources’)</li> </ul>
A- Assess and be Aware of what’s normal for you	<ul style="list-style-type: none"> <li>• Information on the A of ACT (information on how to know what is normal, and how to assess and be aware of their Head and Neck area)</li> </ul>
C- Check for changes regularly	<ul style="list-style-type: none"> <li>• Information on the C of ACT (e.g. information on potential signs or symptoms of recurrence)</li> <li>• Link to film on mouth self-examination</li> <li>• Animation film of how and what symptoms to check for and tips on how to check, overview of the ACT message</li> <li>• Reminder function (for regular symptom checking)</li> <li>• Symptom checker/diary function with prompts</li> </ul>
T- Tell your hospital team about any concerns you have	<ul style="list-style-type: none"> <li>• Information on the T of ACT (Personalized hospital contact information in app/booklet- inputted during education and support session by nurse)</li> <li>• A clear ‘green button’ to press to call the hospital team</li> <li>• Options of contacting the hospital via phone, text and email.</li> <li>• Reassuring information about seeking help and the benefits of seeking help early.</li> </ul>
Caregiver information	<ul style="list-style-type: none"> <li>• Information targeted at the caregiver, in terms of how they can help the patient while they are on PIFU</li> <li>• Information provided for the caregiver for helping the patient with contacting the hospital and with checking for changes.</li> <li>• Information on how the caregiver can look after themselves and their own wellbeing</li> </ul>
Information on PIFU	<ul style="list-style-type: none"> <li>• Information on the key benefits of PIFU</li> <li>• Film by the study principal investigators on the key aspects of PIFU</li> </ul>
Support section	<ul style="list-style-type: none"> <li>• Links to external websites and support organizations (including HNC specific and general cancer charities)</li> <li>• Links to existing online forums to provide peer support</li> <li>• Contact details of allied health professionals inputted into app/booklet (where relevant).</li> </ul>
Worries and concerns section	<ul style="list-style-type: none"> <li>• Information on managing fear of recurrence (including tips for managing fears, links to support organizations and resources, resources to help with relaxation and wellbeing)</li> <li>• Confirmation that patients on PETNECK2 are at low risk of recurrence</li> <li>• Information on concerns about the effects of treatment</li> <li>• Signposting links to getting professional emotional support</li> <li>• Information to address concerns about being on PIFU</li> </ul>
Keeping healthy section	<ul style="list-style-type: none"> <li>• Information on ‘keeping healthy’ with sections on lifestyle and links to resources (including ‘eating a healthy diet’, ‘becoming more active’, ‘self-care for general wellbeing’, ‘maintaining good oral health’, ‘giving up smoking’, ‘reducing alcohol intake’)</li> </ul>

barriers to PIFU they may have. Different recruitment strategies may be needed in future work, such as through key community group leaders and networks [50,51]. It is possible that having family members present for a few interviews/workshops impacted on responses, however most participants preferred to participate alone. Another issue encountered was the shift to online workshops due to the COVID-19 pandemic. As larger groups of 15–20 were not deemed to be feasible online, we organized a greater number of workshops with fewer participants in each. However, patients seemed able to discuss their views and had more opportunity to do so due to smaller numbers. Other benefits for patients included convenience and time-saving due to not having to travel. We found that the theoretical models used in the intervention development were fit for purpose, however acknowledge the limitations of using the COM-B model, which could be critiqued for not accounting for the complexity and variability in behavior. The COM-B model is often used alongside the Behavior Change Wheel intervention development framework [27], but using it alongside the more flexible intervention mapping process [25,26] was straightforward and did not create any difficulties. Using intervention mapping [25,26] allowed us to incorporate psychological change components (e.g. fear of recurrence) as well as behavior change components. SDT [33] usefully informed the content of the intervention and training package, in order to promote, to the extent possible, autonomous motivation for PIFU. Patient experiences of behavior change and how the intervention relates to aspects of the COM-B and SDT will be explored in the feasibility study.

#### 4.2. Practice implications

The ‘ACT now & check-it-out’ intervention will be delivered in the first trial of PIFU (PETNECK 2) in HNC patients to date [22]. The development of intervention support packages for patients on PIFU is important, as this relatively new model of follow up is now a key NHS priority being implemented across different disease groups [14]. If

successful, it is possible that this model of intervention could be modified and used for PIFU pathways in other cancers and diseases. It is also possible that our acronym (ACT) and associated features (e.g., animation film) could be modified for people with other conditions or cancers (e.g. signs of fluid build-up in people with heart failure), as well as in the general population or ‘at risk’ groups, to promote regular self-checking for signs of HNC, and to prompt help-seeking. This is important due to the lack of public health campaigns for HNC and the rising incidence rates [20,21].

Preceding a planned large trial [22], the PIFU intervention and resources will be evaluated and refined through a feasibility study to assess acceptability and feasibility to patients and clinicians. The trial evaluation will assess the effectiveness of PIFU compared to standard surveillance in relation to survival time, patient experience and satisfaction, fear of recurrence, quality of life, health service usage, time to detection of recurrence and cost-effectiveness.

#### 5. Conclusion

In conclusion, we have developed a comprehensive, evidence-informed, theoretically driven intervention to support PIFU in HNC patients, that is strongly grounded in the needs of patients and cancer service providers. A large trial is underway to assess the effectiveness and cost-effectiveness of the PETNECK2 intervention.

**Statement:** I confirm all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story.

#### Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and

its later amendments or comparable ethical standards.

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For the purpose of open access, the author has applied [a Creative Commons Attribution (CC BY) licence] [an 'Open Government Licence'] (or where permitted by the National Institute for Health Research) [a Creative Commons Attribution No-derivatives (CC BY-ND) licence] to any Author Accepted Manuscript version arising.

## CRediT authorship contribution statement

**Brett Jo:** Writing – review & editing, Writing – original draft, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization. **Secher Denis:** Writing – review & editing, Resources, Funding acquisition. **Mehanna Hisham:** Writing – review & editing, Supervision, Funding acquisition, Conceptualization. **Wells Mary:** Writing – review & editing, Resources, Methodology, Funding acquisition, Conceptualization. **Lor-enc Ava:** Writing – review & editing, Methodology, Investigation, Formal analysis. **Rhodes Pat:** Writing – review & editing, Resources, Funding acquisition. **Ozakinci Gozde:** Writing – review & editing, Resources, Funding acquisition, Conceptualization. **Jepson Marcus:** Writing – review & editing, Supervision, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization. **Watson Eila:** Writing – review & editing, Supervision, Funding acquisition, Conceptualization. **Mittal Saloni:** Writing – review & editing, Resources, Project administration. **Matheson Lauren:** Writing – review & editing, Writing – original draft, Resources, Project administration, Methodology, Investigation, Formal analysis, Data curation. **Fulton-Lieuw Tessa:** Writing – review & editing, Supervision, Resources, Project administration, Funding acquisition. **Nankivell Paul:** Writing – review & editing, Supervision, Funding acquisition, Conceptualization. **Duda Joan L:** Writing – review & editing, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization. **Main Barry:** Writing – review & editing, Resources, Funding acquisition. **Greaves Colin:** Writing – review & editing, Methodology, Investigation, Funding acquisition, Formal analysis.

## Conflicts of interest/competing interests

HM -received funding from AstraZenica, Sanofi Pasteur and MSD, been on advisory boards for Nanobiotix, Seattle Genetics, Merck, Seagen, has been employed with Warwickshire Head and Neck clinic Ltd.

## Data Availability

De-identified data from this study are not available in a public archive. De-identified data from this study will be made available (as allowable according to institutional IRB standards) by emailing the corresponding author.

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## Consent to participate

Informed consent was obtained from all individual participants included in the study.

## Consent for publication

Consent for publication was obtained from all individual participants included in the study.

## Materials availability

Materials used to conduct the study are not publically available.

## Code availability

There is not analytic code associated with this study.

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## Appendix B. Supporting information

Supplementary data associated with this article can be found in the

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