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Digitally supported total skin self-examination at home for people treated for cutaneous melanoma: developing and simulating experience of the ASICA intervention.

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ABSTRACT

Objectives: To develop a digital intervention to prompt, support and respond to the outcomes of total skin self-examinations (TSSEs) at home by people treated for cutaneous melanoma.

Design: A complex intervention development study

Setting: Northeast Scotland

Participants: Semi-structured scoping interviews; People previously treated for cutaneous melanoma (n=21). Pilot testing; people treated for melanoma stages 0-2C (n=20); general practitioners (n=6); and a nurse specialist in dermatology (n=1).

Intervention: A tablet-based digital intervention designed to prompt and support TSSEs comprising instructional videos and electronic reporting (including photographs) to a clinical nurse specialist in dermatology with subsequent clinical triage.

Primary and secondary outcome measures: Qualitative assessment of intervention feasibility and acceptability and quantitative assessment of intentions and confidence to perform TSSEs in pilot participants.

Results: The majority of pilot participants were strongly positive and adhered well to the intervention (n=15) with seven of these reporting symptoms of concern at some point during the six month pilot. Four patients complied intermittently, three reporting skin problems at least once during the pilot, and one withdrew. Two patients underwent skin surgery as a result of participating in the pilot, with one proving to have a recurrent melanoma, the other a benign lesion. A number of practical issues to improve the usability of the intervention were identified. The proportion of participants reporting intention to check their skin at least monthly increased during the intervention as did confidence to conduct a skin check.

Conclusions: People previously treated for cutaneous melanoma are prepared to use digital technology to support them in conducting total skin self-examination. An intervention has been developed which is practical, effective and safe and, after addressing minor practical issues, could now be evaluated for clinical outcomes in a randomised clinical trial.

ARTICLE SUMMARY

Article focus: We describe the development and feasibility testing of a complex, digitally supported, behavioural intervention to prompt, support and respond to regular total skin self-examination by people previously treated for cutaneous melanoma.

Key messages: A feasible and acceptable intervention has been developed. Participants in the pilot study adhered well and were highly positive about their experience of using the intervention. Preliminary evidence suggests that the intervention can help sustain regular total skin self-examination by people previously treated for cutaneous melanoma and lead to prompter resolution of concerns, and potentially early detection of recurrence.

Strengths and limitations of this study:

- The study involved key stakeholders and followed a well-evidenced and iterative approach to developing theory, devising an intervention and establishing its feasibility and potential efficacy in a real-world clinical environment.
- The pilot is small-scale which has implications about the representativeness of our participants. A randomised clinical trial is now required to inform wider implementation.

INTRODUCTION

People previously treated for cutaneous melanoma are at risk of recurrences and new primary melanomas. The early detection of these events is one of the key aims of structured follow-up programmes for cutaneous melanoma and these are supported by guidelines in most countries.[1,2] Delivering effective structured melanoma follow-up to a growing population of eligible people is burdensome to health services, especially since many recurrences and new primaries occur in the intervals between structured melanoma follow-up visits.[1] In recognition of this, many experts advocate that patients treated for cutaneous melanoma should be instructed to perform total skin self-examinations (TSSESs) and to conduct these examinations regularly in the intervals between structured follow-up visits.[3]

There are reasons to believe that such regular TSSESs performed by people previously treated for cutaneous melanoma could yield marked survival benefits, for example, those who detect their own recurrences may have as much as a 63% reduction in mortality.[4,5] Furthermore, a review of the efficacy of skin self-examination for early detection of melanoma found evidence of high specificity (83% to 97%) for the detection of new lesions.[6] Sensitivity was lower but the included studies were not conducted with those previously treated for melanoma. It seems likely, although it cannot be stated with certainty, that a previous diagnosis of melanoma would increase knowledge and awareness with a corresponding increase in sensitivity. There is also some evidence, from a US case control trial and Australian modelling paper, that skin self-examination can reduce the development of advanced disease and facilitate early detection of recurrence by people affected by melanoma.[7,8] It is hoped that support to perform TSSEs could enable both recurrences and new primaries to be detected at an earliest stage when a cure may still be possible. The risk of recurrence in cutaneous melanoma is influenced by the stage of disease at diagnosis.[8] Less intense follow-up regimens have been advocated for those with early stage

disease at diagnosis (Stage IA, IB, IIA) and effective and sustained TSSEs could be particularly important in underpinning these.[8] Equally, however, since all patients treated for cutaneous melanoma are at risk of recurrence, effective TSSEs could be viewed as having a role as an adjunct in follow-up irrespective of clinical stage at diagnosis

Despite this, TSSEs education and practice appears suboptimal with 70% of American melanoma patients indicating that they have never been advised to do it.[9] We have found similar evidence of under preparation to conduct and performance of TSSEs in a UK population.[10]

Evidence from randomised trials suggests that people can be appropriately trained to conduct TSSEs.[11,12,13,14,15] However it is less clear whether TSSEs, once learned, can be sustained. Recent qualitative evidence suggests that the intention to conduct TSSEs wanes with time.[10] Digital technologies are becoming more prevalent in society, with a recent report that 49% of UK homes own at least one smartphone, tablet and computer.[16] More and more people are using personal electronic devices such as tablets and smartphones to obtain health information and to interact with healthcare providers.[17] This paper reports the development, pilot testing and preliminary evaluation of the Achieving Self-directed Integrated Cancer Aftercare (ASICA) intervention, a tablet computer based application designed to prompt and support total skin self-examination at home by people treated for cutaneous melanoma.

DEVELOPING A DIGITAL INTERVENTION – METHODS AND RESULTS

Overview

Our approach was based on the key development activities outlined in the MRC Framework for the development and evaluation of complex healthcare interventions.[18,19] Our approach comprised a number of activities which:

A) **Generated evidence** on how technology has been used in cancer follow-up, how people with melanoma perceived this technology that could be used to support them to conduct TSSEs, and how to target technology at those patients with most potential to benefit.

B) **Identified and developed theory** grounded in Information Motivation Behaviour Skills (IMB) as an explanatory model combined with Control Theory to underpin the theoretical development of the intervention.[20,21,22] Using this model the components for a potential intervention were theorized in consultation with experts in behavioural science, and the mechanism for the whole intervention to prompt, record and respond to TSSEs by patients in their own homes was conceptualized and implemented using Behaviour Change Techniques (BCTs).

C) **Modelled the process** of delivery of the combined components of the intervention. A major challenge to this project was to combine the theory and evidence-based components into a viable intervention and we used innovative methods to simulate the full intervention. This was done using an experience laboratory event facilitated by experts where healthy volunteers simulated the processes of the theorized ASICA intervention.

D) **Assessed the feasibility and acceptability** of the prototype ASICA intervention through a pilot exercise with a group of patients supported by a nurse specialist in dermatology.

A) Generating the evidence to use and target technology

Evidence was derived from three sources. First, a systematic review was conducted to determine how technology has been used to support people with cancer.[23] Second, interviews were conducted with 21 people previously treated for cutaneous melanoma.[10] Third, clinical data were sought and obtained where available on recent recurrences and new primary melanomas diagnosed in Northeast of Scotland.[3]

When integrated, this evidence suggests that:

(a) The technology to deliver cancer follow up care remotely is available, safe and acceptable

(b) People treated for cutaneous melanoma can

- See the benefit of conducting TSSEs but feel ill-equipped to perform it properly, safely, regularly and sustainedly.
- Can see the potential of technology to support them in this endeavour and want to be shown how to conduct sequential TSSEs and then reminded when and how to do it. That this process could be supported by repeated reference to an instructional resource (e.g. a video) and self-reference (e.g. a digital skin map).
- Want to be able to report their findings quickly to a specialist and be reassured that the specialist would check their report and respond quickly if there were concerns
- Would welcome the potential opportunity to engage with healthcare professionals from their own homes without inconvenience (travel, time off work, parking). This was especially so for rural dwellers.

(c) Approaches to monitor potential recurrence need to be developed carefully, and should not replace current hospital based follow-up until their safety and efficacy have been proven.

(d) Recurrence is common, so an intervention to support TSSEs should be implemented within a month or so of diagnosis to afford maximum benefit.

B) Identifying and developing theory

The research team included an academic GP, a health services researcher, two health psychologists, and two computer scientists) Together, they had expertise in intervention development and evaluation, behaviour change and translating behavioural interventions into programmed computer applications. The chief investigator (an academic GP) first conceptualized the aims, processes and outcomes that the digital intervention should achieve. The overriding aim of the intervention was to prompt the performance and reporting of good quality TSSEs by people previously treated for cutaneous melanoma. In order for this to happen, individuals using the technology required to be shown how to conduct the behaviour in an optimal way (TSSEs) and then to be prompted to conduct the behaviour regularly. They also needed to be able to remind themselves how to undertake this relatively complex behaviour each time they were required to do it. The intervention was then required to transmit the information resulting from each patient's TSSEs to an overseeing clinician who would either record and acknowledge them or respond appropriately (i.e. employ clinical triage) when a patient did identify a concern. Consideration was given to the most appropriate theoretical model able to inform an intervention to achieve these aims, support the necessary processes and deliver the desired outcomes.

It was decided that the Information-Motivation-Behaviour model offered the most promise in explain the use of TSSEs.[20] Using this model the components for a potential intervention were theorized and the mechanism to prompt, record and respond to TSSEs by patients in their own homes was conceptualized. This is illustrated in figures 1a and b.[20,21] While the explanatory outline was based on the IMB, the results of interviews conducted in Stage A indicated that, while patients required more information, they were highly motivated and we therefore required a theory that guided the translation of motivation into action. The process of intervention was therefore additionally guided by 'Control Theory' as this theory deals

with the process of changing behaviour from a pattern that fails to achieve the person's goal to one that achieves their goal.[20,21,22]

These theories outline the process of change and give some guidance on the behaviour change techniques (BCTs) i.e. the active ingredients required to change behaviour.[24] Some techniques are required to develop the knowledge and behavioural skills to enact the behaviour (e.g. demonstrating the behaviour, rehearsing/practising TSSEs), some to address the person's motivation to engage in the process of TSSEs (e.g. providing information on health consequences of the behaviour (TSSEs), using a credible source for the information), some to enhance confidence that they could conduct TSSEs successfully (e.g. mastering the skills necessary), and some to enable self-regulation of action, especially remembering when to act (e.g. prompts and cues) and the sequence of actions necessary for the optimal clinical outcome (e.g. Action plans or 'implementation intentions'). Action Plans have been shown to be effective in enabling the individual to turn their decisions or intentions into behaviours that achieve their goals. That is, patients who have decided to do TSSEs would make a clear plan when, where, and how they would do the examination. Planning 'how' might include involving someone else (e.g. to examine areas of skin that they cannot easily see themselves), and planning 'when' to receive a reminder. It is important to distinguish a decision (more like an intention which might be forgotten) from a plan, which is a much clearer statement about future action and has been shown to enhance recall of intention and performance of the planned behaviour.[25]

The whole research team first discussed the fidelity of the theory to the delivery of the intervention, and then worked together to map a theoretical structure for the intervention. The intervention tackled the issue of intentional and non-intentional non-adherence (including forgetting, deferring, avoidance or deciding it is unnecessary) by the prompting to undertake

TSSEs and checking adherence by adding certain active features, for example, the marking of skin maps or by asking participants how long the personal skin check took. This gave an indication of thoroughness and provides information on those who do it more quickly because, for example, they have other commitments, or those who choose to adopt avoidance. This allows the monitoring of adherence and engagement. A strategy to identify avoidance is very important since, without it, clinicians could be making clinical decisions and providing clinical advice based on incorrect information.

C) Modelling the process of delivery of the intervention

Experience Laboratory Event

An Experience Laboratory event was held in May 2013 at Glasgow School of Art's Centre for Design Innovation, in Forres, Moray.[26] This facility enables the creation of different environments to simulate real-life situations. The processes of delivery for the ASICA intervention, including simulation of the clinical sequences, were developed for use at the event. This included a simulation of the information and TSSEs demonstration for a potential supporting digital application, which was produced and embedded upon a hand-held tablet computer, with guidance from experts in design and presentation. Three locations were constructed: a patient bedroom **[Photo 1]**, a GPs surgery, and a clinical nurse specialist's office, the latter two being equipped with video-conferencing capability. The intervention components included in the simulation were: the cue to action (i.e. the prompt to complete TSSEs); the instructional video (showing how to conduct TSSEs); the skin-map (to be used while conducting TSSEs) and the report sent to health professionals (following completion of TSSEs).

The Experience Laboratory event was facilitated by design experts and attended by five patient volunteers (one supported by a helper) unaffected by cutaneous melanoma who

performed a simulation of the theoretical intervention (as shown in figure 1b), a GP, a clinical nurse specialist in dermatology and the researchers.

Following an initial briefing session an existing instructional video produced by MASCOT (Melanoma Action and Support Scotland) describing how to conduct TSSEs was viewed by all participants. Two scenarios were constructed and enacted by each of the patient volunteers. In the first, the volunteers were asked to perform TSSEs at which no problems were detected. In the second scenario, the volunteers conducted TSSEs at which a new mole was detected. In this latter scenario the patient attended the GP surgery location for a video consultation between themselves and the co-located GP, and the remote clinical nurse specialist.

A professional TV company filmed and edited a video of the proceedings. At the conclusion of the day all participants viewed the video and a feedback and a debriefing session was held.

Integrating components and processes of the ASICA intervention

The Experience Laboratory enabled participating stakeholders to articulate and agree the benefits which the ASICA intervention could deliver to recipients. Furthermore, the activity enabled the theoretical components of the intervention to be operationalized in the simulation in order to gain insight into how well they integrated and served the purposes for which they were intended i.e. to support the mechanism of prompting, recording and enabling a response to TSSEs. The Experience Laboratory also enabled the researchers to gain insight into the detailed processes and the sequence in which they should occur to support the effective operation of the ASICA intervention. These were: the language used; training of the user; reporting to the specialist, and receiving feedback from the specialist. The detailed learning achieved on each component is also summarised in appendix 1.

Combining processes and components in a prototype intervention

As a result of the Experience Laboratory event, the detailed components and processes identified and developed during the theoretical stage were integrated into a prototype ASICA intervention, including a supporting digital application which was designed to run on a Google Nexus 7 tablet computer. Distinct from the application were several other components including:

1. The structured training session required at inception.
2. The initial and recurring cue to action required to remind the patient to conduct a personal skin check. The need for this to be a separate trigger (sent by email or text message to the recipient's mobile phone) was necessary to avoid the risk that the tablet was used only for skin checks with the risk that the prompt would not be received.
3. The specialist response, a telephone call from the overseeing specialist nurse within 24 hours, since both the human contact and immediacy were perceived as important reassuring factors when a patient could be anxious.

Based on the Experience Laboratory findings, the prototype intervention was adjusted for piloting. The need for clear and simple language unifying the application and supporting processes was perceived to be key to user engagement and intervention adherence. Within the digital application, language was made consistent with the language introduced at the training session. This was carried over into an animated instructional video which was produced and divided into chapters based upon body areas and used as a means to demonstrate and remind users about the specific behaviours required to check their body. Conducting the personal skin check using the application was designed to follow a logical sequence supported by a check-list for self-monitoring of completion. The process of feeling for lumps in regional nodal areas was routed so that only the appropriate nodal area was examined by each patient.

Patients are also able to check an integrated individualized skin-map (formed of a series of professionally produced clinical photographs of each patient) to determine whether skin lesions were new or changing. This function was further supported by the application storing previous reports/images for future reference. At the conclusion of the skin-check the ASICA application delivers a message that either no problem has been reported, or in the event that a symptom concern has been raised, that a specialist will be in touch within 48 hours with further advice. In either eventuality, the completion of the TSSEs is recorded and acknowledged giving a sense of completing the processes in a way that provides feedback and reassurance; this acts as a reward for completing the behaviour with the aim of reinforcing the behaviour so that individual patients will keep using the ASICA application.

D) Pilot study of the feasibility and acceptability of the prototype ASICA Intervention

The prototype ASICA intervention, including the supporting digital application, was subject to a pilot study of feasibility and acceptability amongst 20 people who had previously been treated for cutaneous melanoma.

Recruitment

Six practices were purposively selected to represent geographical spread within the NHS Grampian region of Scotland, and a GP from each was invited to a training meeting to have the protocol explained. The lead GP at each practice identified and approached potential participants for pilot study. Eligible patients were aged over 18, had been diagnosed and treated for cutaneous melanoma within the preceding five years, were currently receiving hospital-based follow-up, and had no nodal involvement or metastases (i.e. in-situ to stage 2C). The 20 people agreeing to participate were identified to, and approached by, the research team. The characteristics of participants are shown in table 1. Recruits attended the Medical Illustration department at the University of Aberdeen to have a full personal body mapping

digital photography taken. These were subsequently hosted on a secure server and could be accessed by individual patients to refer to during subsequent skin checks.

Participant Training

Three training sessions (each of two hours duration) were held in Aberdeen. The meetings followed a structured programme. Participants were introduced to the study and its purposes. The fact that the intervention was experimental (and additional) to their ongoing follow-up was stressed to ensure default from follow-up was not suggested. Participants were instructed in the use of the application and tablet, including how to access their digital skin maps, and their understanding and ability to comply checked. Patients were given detailed instruction manuals for both the tablet and the application. The project researcher arranged an individual meeting with one individual that was not able to attend the training sessions. To prepare for a future clinical trial a questionnaire was modified, with permission, from one used previously.[12,13,14] The questionnaire (included as appendix 2) sought information about respondents' skin cancer history, their skin self-examination practices and intentions, their attitudes, beliefs, self-efficacy and intentions about conducting skin self-examination, the Hospital Anxiety and Depression scale, information about comorbidities and their demographic characteristics. Participants were asked to complete the questionnaire upon arrival at their initial training session. They were then sent the questionnaire again at the conclusion of the pilot.

Process

Participants were sent a monthly email reminding them that it was time to conduct their personal skin check. Upon receipt of the reminder it was intended that they would use the ASICA application to help them systematically examine their skin and through the application they were able to view the integrated instructional video chapters to enable them

to do this. A structured electronic report pro-forma was available for completion. Where a new lesion was identified either at the previous melanoma site or a new one, participants were able to complete a free-text description and/or attach a photograph taken using the tablet's camera function. Completed reports were then sent electronically to a secure and remote server. The returned reports were communicated to, and reviewed by, an overseeing nurse specialist. Figure 1 illustrates the TSSEs procedure supported by the ASICA application. Where patients had identified concerns they were contacted by telephone within 24 hours by the reviewing nurse specialist who either provided reassurance or invited them to an upcoming clinic for subsequent review. At the conclusion of the pilot study all continuing participants were invited to attend for a total skin examination at their GP surgery and 15 accepted this invitation and attended. Three declined, one because he has regular private skin checks, one because he was on holiday at the time of the appointment, one because he was undergoing treatment for metastatic melanoma, and one did not attend.

At the conclusion of the pilot the project researcher SH contacted all participating patients and the overseeing clinical nurse specialist to conduct a brief telephone interview. Questions focused on patients' perceptions of the strengths and weakness of the ASICA application and how it had functioned. The interviewer also gathered information about how well the technical aspects of the intervention had worked from the nurse-specialist and patient perspective.

Pilot Study Results

a) Feasibility

Details of the number and regularity of the skin checks participants performed during the pilot can be seen in table 2. Of the 20 participants, 15 complied well and eight reported no symptoms during the six-month pilot, seven reported at least one issue to the overseeing

clinical nurse specialist. Most issues were resolved by submitting further images under the direction of the specialist nurse, with a corresponding telephone call. Two participants subsequently had the lesions spotted during personal skin checks removed, one was a recurrent melanoma and the other was a benign lesion. Of the three less compliant participants one regularly checked only his face where his original primary had been, another checked selected areas less regularly, citing work pressures and lack of time to conduct TSSEs. Another, a busy mum who stated she found it difficult to make time to conduct a TSSEs, checked their skin only once, on that occasion reporting three issues of concern to the overseeing nurse specialist. One participant withdrew for undisclosed personal reasons.

With respect to the technical operation of ASICA the nurse specialist stated that on the few occasions when photographs of new skin lesions had been submitted by participants these were typically of insufficient quality on which to base clinical judgements. However, in almost all cases he was able to contact the patient and direct them to take improved images. As a result guidelines to take good quality images have been incorporated into the revised app.

b) Acceptability

Patients were largely positive about their experience of using ASICA. The user-friendliness of ASICA was highlighted, along with views that participation supported good habits, allowed participants to become familiar with their own bodies, and provided them with empowerment and reassurance. Table 3 describes comments which reflect these themes. Technical issues raised by patients fell into three categories. There were minor issues with the interface (e.g parts of electronic buttons being obscured) which have been modified. Some patients, especially those in the more remote rural areas, were troubled by issues related to their internet connection. These are less easy to resolve but are likely to be more common in

this particular geographical location than in the majority of the rest of the UK. Government initiatives and technological advances will help going forward in this regard. Similarly, there were some issues with the hardware, for example a malfunctioning charger in one case and a damaged screen in another.

c) Piloting trial procedures

Sixteen participants completed and returned the questionnaire at baseline and outcome. The data are not presented in detail. There were non-significant increases in the proportion of respondents indicating that they intended to check their skin at least monthly, and in the proportion indicating that they would be confident to perform total skin self-examination. These data will however, be informative in determining power for a subsequent randomised trial.

DISCUSSION

Principal findings

The authors have developed a feasible clinical intervention process based on a digital tablet-based application to prompt, record, and respond to regular total skin self-examination by people previously treated for cutaneous melanoma. This has proven to be acceptable and safe for patients to use. There is also preliminary evidence that it can help reinforce and sustain TSSEs in a way that has not previously been possible. Further, there is some early evidence that it can bring new skin problems to medical attention sooner than would otherwise have been the case. It must also be noted however that the fact that a minority of patients did not comply, or complied only partially, indicates that ASICA will not compel all patients to conduct regular TSSEs or might require tailoring for some patients.

Strengths and limitations

Strengths

The approach adopted for developing the ASICA intervention had several inherent strengths. Developing interventions that employ digital technologies to deliver aspects of healthcare in a completely new way is immensely challenging. For this reason our approach benefited from employing the structured, iterative and well-rehearsed approach advocated by the MRC framework.[18,19] The use of the Experience Laboratory allowed simulation of the complete intervention, integrating components based on theory and evidence. The experience of the team in following this approach and the strong theoretical underpinning of the IMB and Control Theory models allowed the project to be phased and focused.[20,21] We involved key stakeholders – potential patients, clinicians, technology specialists, behaviour change intervention specialists, health service researchers – at each stage of the process so that their perspectives were identified and incorporated throughout. Furthermore, adopting this multidisciplinary approach enabled an ongoing understanding of the full spectrum of potential challenges and caveats which the intervention was required to overcome, complemented by an ability to exploit the enablers perceived by each group. We were also able to ensure that we optimised the potential of the ASICA digital application, identifying the necessary processes and components, and ensuring that they were developed and embedded within the intervention in the most effective way.

Limitations

Some limitations must be acknowledged. The pilot was conducted on a small scale within Northeast Scotland. Clearly, this has implications about the representativeness of our participants. In terms of the whole Scottish population they were relatively affluent and also willing to learn about technology. It was assumed that all patients were physically capable of using the tablet and the application, but one could not use their fingers and required to be

supplied with a stylus. There were other disabilities that were not provided for, for example poor eye-sight, lack of proficiency in English and restricted physical movement. A range of adherence was observed during the study and we were unable to understand this in detail. ASICA, as currently configured, will not suit everyone, but it may be possible to tailor it to individual need. While the developed intervention may have greater value and relevance among people familiar with technological advances and in localities where the clinical service is delivered to patients living remotely from the clinical centre, it is likely to have utility among a broad range of patients after melanoma diagnosis and treatment. This view is supported by noting that people with melanoma from stage 0-2C were willing to take part.

These limitations must be viewed against the backdrop of societal trends to embrace modern technology, and an increasing appetite amongst clinicians and policy makers to diagnose and manage skin cancer using digital means. A recent review, for example identified 40 applications of divergent quality and developmental rigour, for monitoring and diagnosis of pigmented skin lesions.[27]

Context with other studies

Where interventions have been specifically developed to improve TSSEs practice, and subjected to randomised trial the results have been disappointing, although the recruited patient groups have been different to this pilot study. Two randomised trials, one in a general US primary care population and another in Australian men over 50 at increased risk but with no previous melanoma, educated using brochure or video demonstrations only, reported increased TSSEs practice for 3-7 months, with participation returning to baseline after one-year.[11,12,13,14] A further study, employing a nurse or physician delivered an educational module supported by a personal skin map to US patients but referred to a secondary care pigmented lesion clinic, reported significant increases in TSSEs practice at 4 months.[15]

Previous trials are informative to the current intervention for three reasons. First, all three were conducted in patients at increased risk, rather than patients actually treated for melanoma. It is therefore likely, that the target group of the ASICA intervention will be more motivated to conduct and sustain TSSEs than previously studied groups. Second, previous intervention development provides evidence that several of the components developed using health psychology-based approaches and incorporated into ASICA (such as the instructional videos, personal skin maps, cues to action and sample photographs) have the potential to promote and sustain, at least in the short-term, TSSEs in patients who form a lower risk group than the ASICA target population.[11,12,13,14,15] Third, and perhaps most importantly, the interventions previously trialled have comprised one-off educational activities with the issue of videos, booklets or brochures to patients for subsequent personal use.[11,12,13,14,15] ASICA, on the other hand, will use familiar everyday technology to prompt and sustain the behaviour over time, in participant's own homes which should increase the likelihood of success.[28]

Lessons learned from this study

Our experience has taught us that there are evidential reasons to believe that digital technologies can be used to support cancer survivors in their own homes, remote from healthcare facilities and healthcare professionals. We have further learned that people with melanoma see the potential of technology to support their participation in their own follow-up, particularly in the sustained performance and reporting back of TSSEs. Evidence for components of previous interventions that have sustained TSSEs in the medium term has been translated onto a theoretical intervention based on well-evidenced theoretical models using the Behaviour Change Techniques Taxonomy v1 to implement the active behaviour change mechanisms.[29] We have learned that a skilfully facilitated experience laboratory can be used to provide rapid feedback on a theoretical and simulated intervention prior to its

initial development and testing in a full-scale pilot trial. Finally, we have used carefully assembled theory and knowledge to build a working proto-type of an actual digital intervention to support TSSEs by people previously treated for cutaneous melanoma. This has functioned well in a real world pilot. It has succeeded in actually supporting, and responding to TSSEs, in a group of patients, who have appreciated and enjoyed using it. We have learned that it is a feasible and desirable intervention. We have also learned about the minor modifications that are required to proceed to a definitive clinical trial employing the ASICA intervention. Such a trial, conducted at several UK centres to ensure wider applicability, should now follow shortly, so that we can consolidate the promising findings reported here with definitive evidence of ASICA's role in future melanoma follow-up.

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CONTRIBUTORS

PM conceived the original intervention. SH conducted the initial exploratory interviews. The theoretical intervention was mapped by PM, SH, MJ, JA and translated into a working prototype by JM and MD, with advice on national implementation potential from FW. JM and MD developed the patient training sessions and materials, and the training was delivered by PM, JM, MD and SH. BB delivered the intervention. PM, SH, MD and FW generated and analysed the data. PM wrote the manuscript with contributions from all authors.

COMPETING INTERESTS

All authors have completed the Unified Competing Interest form at www.icmje.org/co_disclosure.pdf (available on request from the corresponding author) and declare that (1) None of the authors have support from any commercial company for the submitted work; (2) PM, JA, BB, MD, SH, JM, FW and MJ have no relationships with any

commercial company that might have an interest in the submitted work in the previous 3 years (3) their spouses, partners or children have no financial relationships that may be relevant to the submitted work; and (4)) PM, JA, BB, MD, SH, JM, FW and MJ have no non-financial interests that may be relevant to the submitted work.

ETHICS APPROVAL

Full ethical approval for the interviews with people previously treated for melanoma study was granted by the North of Scotland Research Ethics Committee on 2nd May 2012. (REC reference number: 12/NS/0039). Full ethical approval for the pilot study was granted by the North of Scotland Research Ethics Committee on 10th June 2013. (REC reference number: 13/NS/0062)

STUDY SPONSOR

The University of Aberdeen is the study sponsor. PM, JA, MD, SH, JM and MJ are employees of the University of Aberdeen but all researchers were independent from the sponsor and funders in study design, the collection, analysis and interpretation of data, the writing of the article and the decision to submit for publication.

DATA SHARING STATEMENT

Process data about how ASICA performed during the pilot exercise and which does not identify patients, along with the technical specifications of the ASICA digital application may be available upon application to the corresponding author.

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Table 1: Characteristics of pilot study participants

ID	Age	Gender	Place of Residence*	Date of Mel Dx	Site	Stage
001	46	F	Accessible rural	2010	Arm	1.1mm Stage 1B
002	49	F	Other urban area	2012	Knee	0.5mm Stage 1A
003	72	F	Accessible rural	2013	Arm	0.4mm Stage 1A
004	69	M	Urban	2013	Breast	0.8mm Stage 1A
005	62	M	Remote rural	2012	Eyelid	M in situ Stage 0
006	66	F	Remote rural	2011	Cheek	0.3mm Stage 1A
007	72	M	Remote small town	2009	Cheek	2.8mm Stage 2A
008	70	M	Remote small town	2012	Shoulder	0.3mm Stage 1A
009*	41	F	Remote rural	2011	Back	>1mm
010	67	F	Accessible rural	2009	Arm	3mm Stage 2A
011	78	M	Remote small town	2008	Eyebrow	2.6mm Stage 2A
012	42	F	Accessible small town	2011	Back	M in situ Stage 0
013	75	F	Accessible rural	2009	Thigh	1.1mm Stage 2B
014	67	M	Accesible rural	2013	Shoulder	2mm Stage 2A
015	46	F	Accesible rural	2011	Abdomen	0.6mm Stage 1A
016	72	M	Accessible rural	2011	Forearm	1mm Stage 1B
017	65	M	Accessible rural	2014	Shoulder	M in situ Stage 0
018	69	M	Remote rural	2009	Shoulder	1.5mm Stage 1B
019	44	M	Accessible rural	2012	Abdomen	1.5mm Stage 1B
020	44	F	Accessible small town	2010	Lower leg	0.42mm Stage1A

Classifications from Scottish Government Urban-Rural Classification[30]

*Staging data were not available for this patient

Table 2: Compliance with intervention and outcome of monthly skin checks

Patient	Month 1 (May)		Month 2 (June)		Month 3 (July)		Month 4 (August)		Month 5 (September)		Month 6 (October)	
	Checks	Changes reported	Checks	Changes reported	Checks	Changes reported	Checks	Changes reported	Checks	Changes reported	Checks	Changes reported
N=8: Complied well, reported no symptoms												
P02	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**
P03	**0**	**0**	**0**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**0**	**0**
P04	**5**	**0**	**5**	**0**	**5**	**0**	**0**	**0**	**0**	**0**	**5**	**0**
P05	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**
P06	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**
P10	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**
P16	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**
P19	**5**	**0**	**0**	**0**	**5**	**0**	**0**	**0**	**5**	**0**	**5**	**0**
N=7: Complied well, reported symptoms												
P01	**4**	**1**	**0**	**0**	**5**	**2**	**5**	**2**	**4**	**1**	**5**	**0**
P07	**5**	**3**	**5**	**5**	**5**	**2**	**5**	**0**	**5**	**2**	**5**	**0**
P08*	**4**	**0**	**5**	**0**	**5**	**0**	**5**	**2**	**5**	**0**	**5**	**1**
P13	**3**	**3**	**1**	**1**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**
P14	**0**	**0**	**3**	**2**	**4**	**0**	**5**	**1**	**5**	**0**	**4**	**0**
P15	**5**	**1**	**0**	**0**	**5**	**1**	**5**	**0**	**5**	**0**	**5**	**0**
P18***	**5**	**1**	**0**	**0**	**5**	**0**	**0**	**0**	**5**	**1**	**0**	**0**
N= 3: Complied less well, reported symptoms												
P11**	**1**	**1**	**1**	**1**	**1**	**0**	**1**	**1**	**1**	**1**	**1**	**1**
P12	**0**	**0**	**1**	**0**	**0**	**0**	**3**	**1**	**0**	**0**	**0**	**0**
P17	**0**	**0**	**0**	**0**	**3**	**3**	**0**	**0**	**0**	**0**	**0**	**0**
N=1: Complied poorly, reported no issues (P20												
P20	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**5**	**0**	**0**	**0**
P09 PATIENT WITHDREW CITING PERSONAL CIRCUMSTANCES MAKING SKIN CHECKS DIFFICULT – NOT CLEAR WHAT THESE WERE												

*P8 diagnosed with recurrent melanoma after excision of lesion noticed during personal skin check

**P11 checked head and neck only

***P18 diagnosed with benign lesions on both legs after excision of lesions noticed during personal skin check

Table 3: Comments from patient interviews reflecting views on usability and acceptability

A USER FRIENDLY DEVICE P03 – "Yes, it was quite clear the actual information that we were given, very clear, beautifully set out, very easy to use and understand. P04 – "Very good. Very good indeed. It's very clear, easy to understand and useful in tips about parting your hair and getting somebody else to check the back of it for you and things like that, yeah, very clear and easy to understand and you know, tips about how to do awkward places on yourself, yes. P05 – "So what I've done is have a good look at myself over the preceding days, if you know what I mean, just as and when it was comfortable. And really handy, when I was getting changes, getting up or going to bed or what have you, in the shower. And then just rattle through the app. P08 – "The animations that were provided I thought were a really good guide, for somebody that's not used to technology it was really simple." P17 – "Well it tells you exactly what you need to know, there's no question about that." P21 – "The instructions were excellent, they were very well laid out. The videos were very helpful showing you exactly what you needed to do and how to check yourself all over."
ESTABLISHING GOOD HABITS P04 – "But the fact that it makes people do it once a month or whatever, it focuses the attention because it's something we'd probably be a bit slapdash with normally." P13 – "The tablet is great. Totally self-explanatory and the videos are very easy to watch and everything so it very easy to do and send off the report. Everything was great." P15 – "It made you really thorough about the skin check procedure. There was no way you could miss anything out. It was really good." P16 – "Yes, as I say, it's all clear and it's really good to see every part of your body…to go through it all in separate stages. Yes, it make you do it all in a through way, which is important, since I'm not getting checked at the hospital anymore, so it's really important that I've got to remember to check my whole body in case something appears."
GETTING TO KNOW MY OWN BODY P01 – "I like having the maps to look at because I've got a lot of moles but I have discovered there might be a blind spot on my arms where it's not really getting my arm – if you know what I mean? P15 – "Without this it becomes very difficult to remember if anything has changed very much since the last time you looked. This was really the first time I've ever looked really closely at my body, and I think to myself "goodness, I didn't realise I have that there before." And then I go back to the body map and – which is a salutary exercise in itself - and see "oh yes, it was there." I suppose it's getting to know your body much better." P17 – "I never used to think about it, but I know what to look for now. If I see something I know what it is, and what to do. Before, I never would have noticed." P21 – "The more I've done it over the period of months, the more that I've gotten used to where everything is on my body, where all the different moles are." P21 – "Before starting this project I probably wasn't really checking my skin that much at all, but since I've been doing this, it's been much more regular and I've been paying much more attention to it.
FEELING REASSURED AND EMPOWERED P09-"I'm very pleased with it, because it's helping me, you feel in control, that you are looking after yourself." P12 – "If somebody is checking it, that can get back to you really quickly, then off to the GP. Very re-assuring." P14 – "And because I was doing it so diligently, I felt good about that." P14 – "It a brilliant idea, especially for people who are a long way away, because you can do a really thorough check, and received professional reassurance without having to travel all the way to Aberdeen."

Figure 1: TSSEs Procedure as Supported by the ASICA application

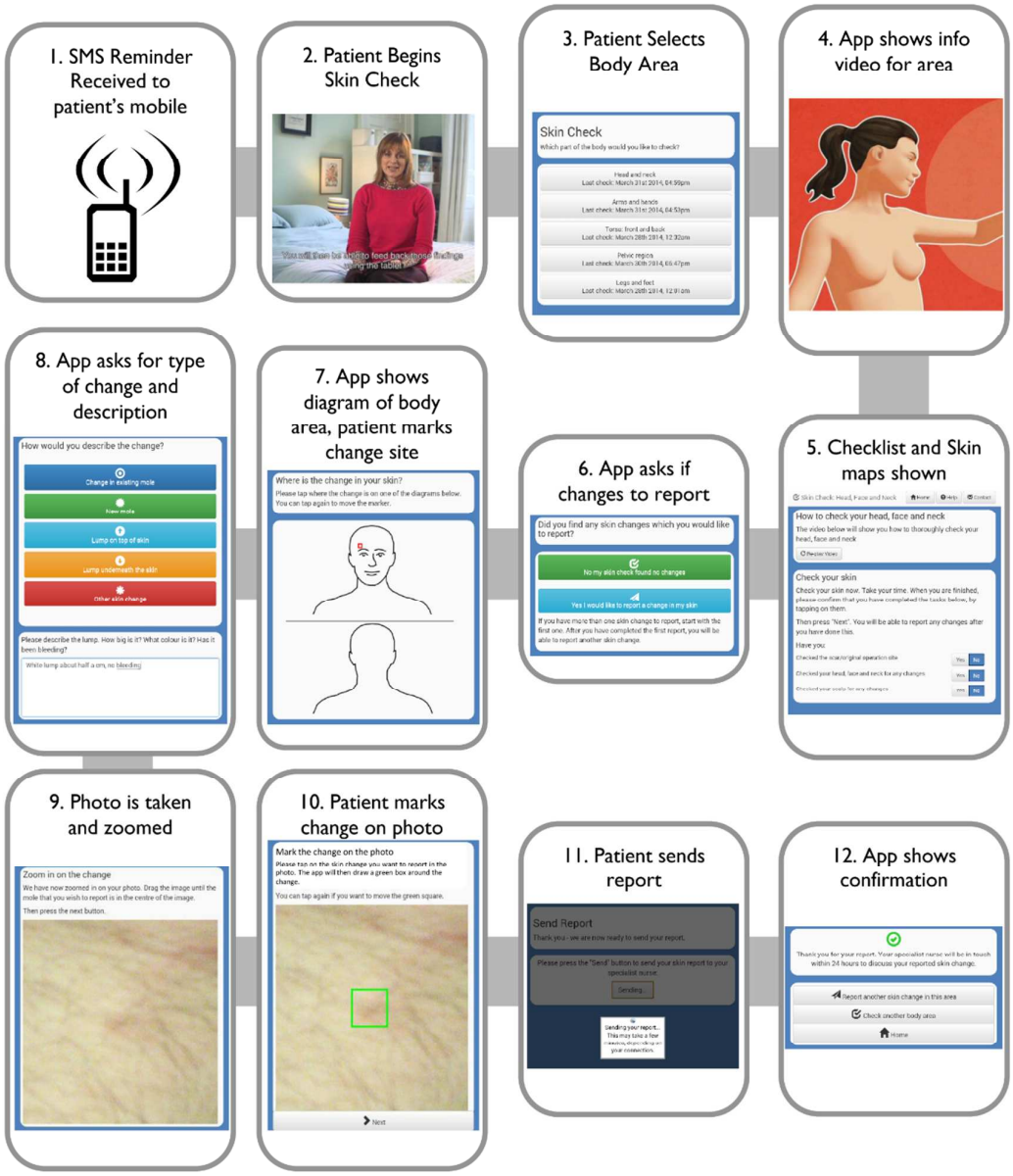


Figure 2a: Model demonstrating theoretical processes of ASICA according to Information-Motivation-Behaviour Skills (IMB) model – adapted from Cowling et al, 2011.

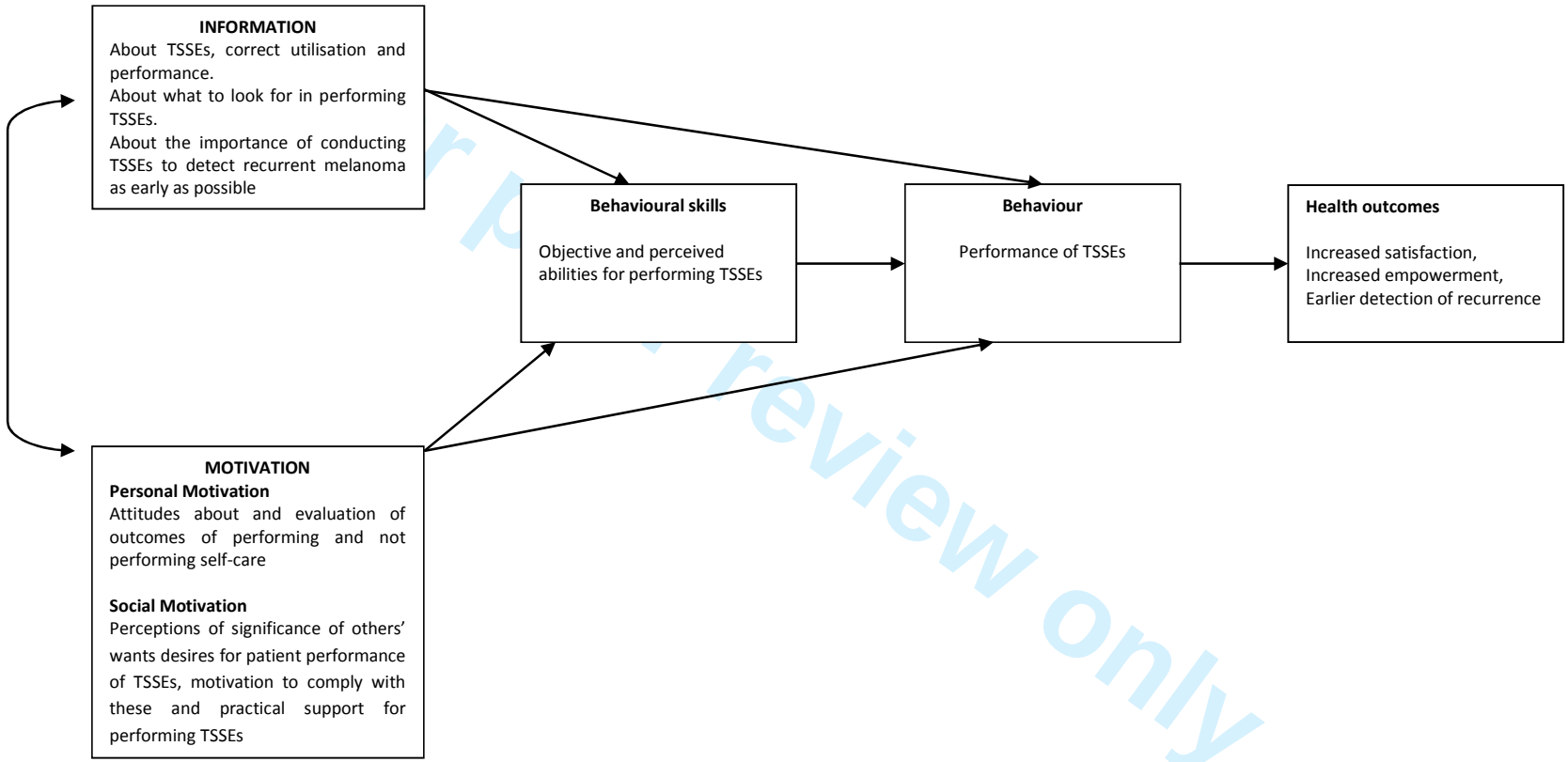
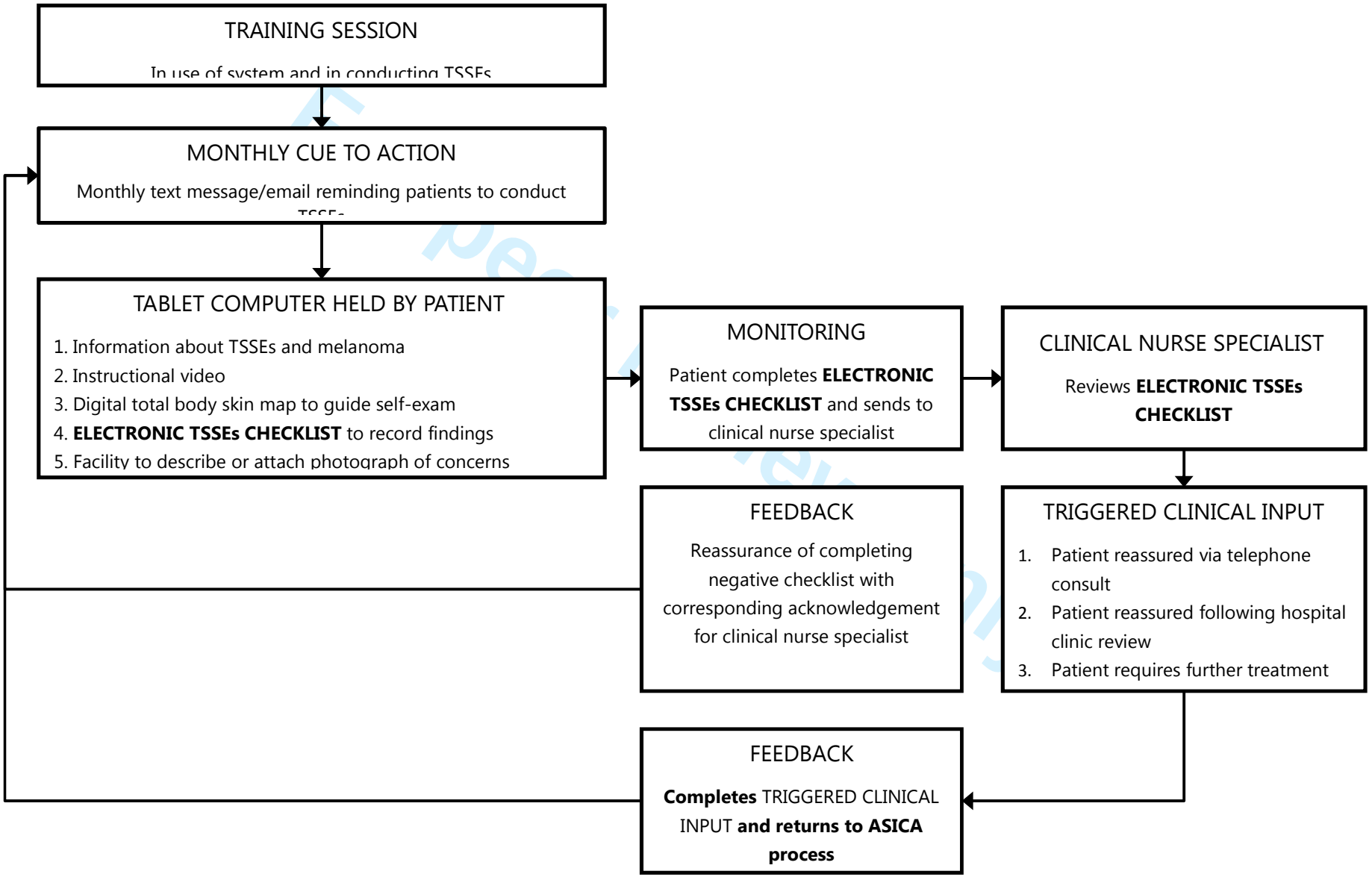


Figure 2b: Schematic demonstrating operationalization of components and processes of ASICA intervention adapted from Cowling et al, 2011.



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APPENDIX 2: Experience lab outcomes

BENEFITS – "WHAT DO I GET FROM THIS?": Developing motivation to engage with ASICA and TSSE

Patient volunteers perceived the following advantages of the ASICA intervention: reduced travel and time; having your own skin map (an aide memoire and evidence if needed); speed and simplicity of the process; rapid reassurance when concerned; raised awareness of caring for my skin and empowerment; feels like the medical staff care for me; secure and I can trust the NHS with my information.

COMPONENTS – "NUTS AND BOLTS TO MAKE IT WORK": Action plans to enable TSSE and maintenance of use of ASICA

THE CUE TO ACTION

The email reminder should be sent at the right time – no point sending it on a Friday evening when the patient will be unable to get a response until the following Monday. It seems sensible, therefore, that these would be sent at the beginning of a week. It was also viewed as sensible to send this to another device/using another mechanism to get round the risk that the tablet may be stored in a drawer between skin-checks.

THE INSTRUCTIONAL VIDEO

The video to be embedded within ASICA had the following aims:

- To introduce self-monitoring
- To incentivise a personal skin check
- To provide persuasion from a credible source
- To provide behavioural instruction
- To demonstrate the required behaviour
- To provide information about health consequences

Comments on the existing video were generally negative. It was described as too long and repetitive and in need of "spicing up." However at least two of the patient volunteers warned that it needed to continue to be comprehensive.

Particular issues for improvement of the video were:

Provide incentive: There was nothing on the video that suggested participants might expect a better outcome by doing a personal skin check. This incentive does not have to be much – it could just be 'By doing this you will get early attention to any problems which the clinic can then deal with' You don't have to say you will save their lives.

Provide Information: Tell us why we are doing this and what we are looking for at each stage. Give us some information about moles (e.g. where are they most likely to be found). Tell us specifically what the things we are worried about look/feel like. Tell us how long the examination will take.

Have an inspiring voice over: The lady on the video was felt to be monotonous.

Make the background less gloomy: The dark background made the video seem oppressive.

Make the video less repetitive: Basic techniques should be explained once, i.e. examining skin and feeling for lumps.

Tailor the video: Give a video of a man for men and a woman for women.

Idealised body: Participants generally felt that a model with an "ideal" body was preferable to more realistic appearance.

Presence of moles: The model should have some moles. We should see them examining the moles as we would want them to do in the behaviour. We should also see how the patient would record this information within the intervention. This should be re-emphasis in each section of the video (i.e. after "The scalp" "The head" "The back".)

Use "point of view" perspective: To differentiate parts of the video where you are looking versus feeling. The video should make it clear that "Looking" and "Feeling" are two very different behaviours. This means that the video should emphasise both behaviours. The video should clearly distinguish between "looking" and "feeling." The video should show what people might see when they "look." Similarly, they should be shown how to "feel". This needs to be tailored to parts of the body – i.e. what are the hands doing when the patient is feeling the back of their legs. Video needs to introduce elements of how to feel for lumps, emphasising those that are practically shown at the training day.

Helpers: The EP day made it clear that people are going to be challenged to examine their back and their scalp. It might be good for the video to introduce the idea of "helpers" and a range of whom these might be – e.g. friends, spouse, carers, parents, children, GPs. It would then be good practice to ask the patients to identify an appropriate helper, a person whom they would most like to involve at recruitment. Perhaps a solution needs to be found for those that can't identify a helper.

Make the video interactive: Split into sections (e.g. head and neck, arms, legs) so that participants can tailor how they do the examination. It will also be important to structure it this way to facilitate a sequence, so that people can tick sections as they go along. The video, therefore, needs to be structured with reference to the check list which will be on the tablet. We should consider having a separate checklist for each part of the body. There is a need, however, to guard against making the system too complicated.

Consequently a new animated video was professionally produced for incorporation onto the tablet.

THE SKIN MAP

What are the technology options for this? Does it need to be broken down or could it be presented as a whole body or video map. It is likely that patients will need to visit Aberdeen for this to be done. Some of Susan's findings from the interviews suggest that this aspect of the project will need to be handled sensitively, one patient reported that having the skin map formed was a humiliating experience. Patients suggested that they wanted to be able to mark any concerns directly on their skin maps. They wanted to able to zoom in to see the detail of the skin map and also to be able to move the photo around, i.e. to see the next body part using the touch screen.

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In consequence arrangements were made at Medical Illustration at University of Aberdeen for each patient to have digital skin map images taken. These were subsequently incorporated onto individual Google Tablets for individual patients.

THE REPORT FORM

The report back form should include options for labelling and a free-text box to explain the outcome, e.g. new mole, new spot, lump, no concerns etc. Patients preferred not to have the option to mark the report urgent – felt that this is something for specialists to decide. Previous report backs should be stored within the app for future reference

PROCESSES – "FLOWS OF INFORMATION"

LANGUAGE

Language used throughout should be chosen with care. In particular, when asking people to perform tasks language should be simple. For example, the term "Personal Skin Check" was perceived as more meaningful, understanding and less daunting to an individual than "Total Skin Self-Examination." Language needs to communicate what they are being asked to do; why they are being asked to do it; how to do it; what might happen when they do it; what the corresponding consequences and further actions of outcomes is.

TRAINING THE USER

Training eventual participants in the pilot exercise will be key.

The issue of engaging participants with the technology is important. The consensus from the plenary was that patients would be more likely to embrace the use of the technology if it was presented in conjunction with the benefits of using technology and the incentives listed about. (e.g. less travel, more control etc). It will also make sense to introduce the technology used as "just something used in healthcare." Patients can manage many much more complex activities and equipment than are being proposed here, for example nebulisers, home oxygen and glucose monitoring in diabetes.

The training must, however, show people how to do the intervention. As one specialist has pointed out one of the main purposes of follow-up appointments is to detect nodal disease. For this reason the individual participants should be shown how to examine their appropriate lymph node basins (neck, groins or axilla. These are practical skills that need to be demonstrated and can be reiterated on the video

However, it will be important not to make the assumption that people will manage to use the tablet/technology. Appropriate training will, and should be delivered. It will also be important to recognise that younger people may be more easily able to engage with the technology. Nevertheless there is a danger of making assumptions according to age stereotypes. We should aim for a standardised non-ageist way of introducing the technology and training people in the system. We should guard against training which is patronising and offensive to older people and too sketchy for younger patients leaving them less well informed.

REPORTING TO THE SPECIALIST

Several functions of the intervention are encapsulated within this step. In most cases patients will be feeding back negative findings. This will convey a sense of reassurance to them and

will, in effect, be the reward for performing the behaviour. In other circumstances a new lesion will be found. In this case, a decision on what is to happen will be available within 48 hours, much quicker than under existing systems. It is likely, therefore that both outcomes will reinforce the behaviour.

There were few concerns from patients about communicating information (including body images remotely). They would assume that security was in place. Technology experts offered "scrambling", "encryption and "cropping images" as further means to ensure security.

FEEDBACK FROM THE SPECIALIST

When the report (no concern) or issue arising is returned participants would want to receive a "report received" receipt. They felt this should be tailored to reflect how long it would take to get a response. It should also provide a phone number which could be contacted if the patient was concerned meantime.

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Appendix 2

This appendix displays the outcome questionnaire developed for use in a proposed future clinical trial of the ASICA intervention. It has been adapted, with permission from an instrument developed by Professor Monika Janda, Queensland University of Technology, Brisbane QLD, Australia. A related baseline questionnaire has also been prepared.

Janda M, Baade PD, Youl PH, Aitken JF, Whiteman DC, Gordon L, Neale RE. The skin awareness study: promoting thorough skin self-examination for skin cancer among men 50 years or older. Contemp Clin Trials 2009,31:119–130

Janda M, Neale RE, Youl P, Whiteman DC, Gordon L, Baade PD: Impact of video-based intervention to improve the prevalence of skin self-examinations in men 50 years or older: the randomized skin awareness trial. Arch Dermatol 2011, 147:799–806.

Janda M, Youl P, Neale R, Aitken J, Whiteman D, Gordon L, Baade P. Clinical Skin Examination Outcomes After a Video-Based Behavioral Intervention: Analysis From a Randomized Clinical Trial JAMA Dermatol. 2014;150(4):372-379. doi:10.1001/jamadermatol.2013.9313.

UNIVERSITY OF ABERDEEN

ASICA Questionnaire (Outcome)

Achieving Self-directed Integrated Cancer Aftercare

All the information that you provide in this questionnaire is confidential. You cannot be identified from any of the answers that you give.

If you have any questions regarding this questionnaire please contact:

For official use only

dot.rural
Transformation through Digital Innovation

Date returned	
Date entered	
Date checked	

What is the purpose of this

questionnaire?

The purpose of this questionnaire is to find out some things about you, your melanoma and your general health.

What if I am not sure how to answer some questions?

Do the best that you can.

Should you have any difficulties with completing the questionnaire, or have any questions about the study please contact:

How long will it take to complete?

It should take no longer than 20 minutes to complete.

Is the information confidential?

All the information that you give is extremely valuable to the study and is treated in the strictest confidence.

What should I do with my completed questionnaire?

After you have filled in the questionnaire please put it in the addressed FREEPOST envelope provided and post it back to us. NO POSTAGE STAMP IS REQUIRED

We would be very grateful if you could return your completed questionnaire as soon as possible.

Thank you

Skin Cancer History

1. **Have you ever had a skin cancer, mole, or other spot/s removed or treated?**

☐ 1 Yes

☐ 2 No → Go to Q4

☐ 3 Unsure/Don't Know → Go to Q4

2. **How many skin cancers, moles, or other spots have you had treated?**

☐ 1 One ☐ 4 Eleven to twenty

☐ 2 Two to five ☐ 5 Twenty-One to fifty

☐ 3 Six to ten ☐ 6 More than fifty

3. **How old were you when you had your first skin cancer, mole, or other spot treated?**

☐ Do not remember

☐ Years old

4. **Are you currently concerned about a spot or mole?**

☐ 1 Yes ☐ 2 No ☐ 3 Not sure

5. **How likely is it, do you think, that you will get skin cancer again at some time in the future?**

☐ 1 Not at all likely

☐ 2 Somewhat likely

☐ 3 Very likely

☐ 4 Don't know/not sure

Skin Self Examination

6. **Have you or someone who is not a doctor or nurse, such as your spouse or partner, <u>ever</u> deliberately checked any part of your skin for early signs of skin cancer.**

☐ 1 Yes ☐ 2 No → Go to Q13

☐ 3 Don't know → Go to Q13

7. **In the <u>past 12 months</u>, have you or someone who is not a doctor or nurse , such as your spouse or partner, deliberately checked any part of your skin for early signs of skin cancer.**

☐ 1 Yes ☐ 2 No → Go to Q13

☐ 3 Don't know

8. **In the past 12 months, <u>how often</u> have you or someone who is not a doctor or nurse checked any part of your skin for early signs of skin cancer?**

☐ 1 One to two times ☐ 3 Five to six times

☐ 2 Three to four times ☐ 4 More than six times

9. **In the past 6 months, <u>how often</u> have you or someone who is not a doctor or nurse checked any part of your skin for early signs of skin cancer?**

☐ 1 One to two times ☐ 3 Five to six times

☐ 2 Three to four times ☐ 4 More than six times

☐ 5 Zero

10. **Thinking back to the last time you or someone who is not a doctor or nurse checked your own skin, which areas of your body did you actually check?**

☐ 1 Face ☐ 8 Feet

☐ 2 Neck ☐ 9 Back of thighs/knees/shins

☐ 3 Upper Chest ☐ 10 Bottom

☐ 4 Arms ☐ 11 Lower Back

☐ 5 Hands ☐ 12 Higher Back

☐ 6 Torso ☐ 13 Back of Neck/Scalp

☐ 7 Front of thighs/knees/shins ☐ 14 Whole Body

11. During your last check, did you use a handheld mirror or full-size mirror to check difficult to see areas of your skin such as your back?

☐ 1 Yes, hand-held mirror ☐ 4 No

☐ 2 Yes, full-size mirror ☐ 5 Don't know

☐ 3 Yes, both

12. During your last check did you have someone to help you see difficult to see areas for example your wife, partner or another relative?

☐ 1 Yes ☐ 2 No ☐ 3 Don't know

13. In the next 12 months, how many times do you intend to check your skin for early signs of skin cancer?

☐ Please write the number in the box.

We would now like to know *how confident* you are about being able to check your skin. Please *circle the number* that best describes your level of confidence for each of the following four questions.

14. How confident are you that you can check your own skin correctly?

1	2	3	4	5	6	7	8	9	10
Not at all Confident				Moderately Confident					Highly Confident

15. How confident are you that you will find the time in the next 12 months to check your own skin.

1	2	3	4	5	6	7	8	9	10
Not at all Confident				Moderately Confident					Highly Confident

16. How confident are you that you will remember to check your own skin at least once a month.

1	2	3	4	5	6	7	8	9	10
Not at all Confident				Moderately Confident					Highly Confident

17. How confident are you that if you find a spot or mole of concern that you will take appropriate action.

1	2	3	4	5	6	7	8	9	10
Not at all Confident				Moderately Confident					Highly Confident

18. When you last checked your own skin, did you find a spot or mole of concern?

☐ 1 Yes → → Go to Q19

☐ 2 No → → Go to Q21

☐ 3 Don't know/unsure → Go to Q21

☐ 3 Did not check my skin → Go to Q21

19. If yes, what did you do?

☐ 1 Watched it for up to one month

☐ 2 Watched it for longer than one month

☐ 3 Showed it to partner/relative

☐ 4 Showed it to a doctor/nurse

☐ 5 Other, please specify ……

20. Over the next six months if you find a spot or mole that you are worried about what will you do?

You may tick one or more options

☐ 1 Show it to a partner, relative or friend

Would you do this:

☐ 1 Immediately

☐ 2 Within a few days

☐ 3 Within a week

☐ 4 Within a month

☐ 5 Other, please specify

☐ 2 Make an appointment with a doctor

Would you do this:

☐ 1 Immediately

☐ 2 Within a few days

☐ 3 Within a week

☐ 4 Within a month

☐ 5 Other, please specify

☐ 3 Contact the specialist nurse

Would you do this:

☐ 1 Immediately

☐ 2 Within a few days

☐ 3 Within a week

☐ 4 Within a month

☐ 5 Other, please specify

☐ 4 Watch it until the next prompt from the ASICA tablet arrives

☐ 5 Watch and wait

☐ 6 Other, please specify ……..

Health Professional Skin Examination

21. Has a doctor or nurse ever deliberately checked any part of your skin for early signs of skin cancer since you received the ASICA electronic tablet?

☐ 1 Yes → Go to Q22

☐ 2 No → Go to Q26

☐ 3 Don't know → Go to Q26

22. In the past 12 months, has a doctor or nurse deliberately checked any part of your skin for early signs of skin cancer?

☐ 1 Yes → Go to Q23

☐ 2 No → Go to Q26

☐ 3 Don't know → Go to Q26

23. In the past 12 months has a doctor or nurse deliberately checked the skin on your whole body? Usually this would involve taking your clothes off at least down to your underwear.

☐ 1 Yes

☐ 2 No

☐ 3 Don't know

24. During your last skin check did the doctor suggest you check your own skin for early signs of skin cancer?

☐ 1 Yes ☐ 2 No

25. Did the doctor show you how to check your own skin for early signs of skin cancer?

☐ 1 Yes ☐ 2 No

Attitudes and Beliefs

For this section of the questionnaire we would like to find out what you think about checking your skin.

26. For each of the following statements please indicate whether you strongly disagree, disagree, agree, strongly agree, or are unsure with each statement. ***Please select only one option for each question.***

	Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree
a. It is important to check my skin for skin cancer even if I have no symptoms	☐1	☐2	☐3	☐4	☐5
b. Checking my skin would make me anxious.	☐1	☐2	☐3	☐4	☐5
c. Checking my skin regularly is a priority for me.	☐1	☐2	☐3	☐4	☐5
d. I could find something suspicious on my skin if it was there.	☐1	☐2	☐3	☐4	☐5
e. If I saw something suspicious on my skin, I'd go to the doctor straight away.	☐1	☐2	☐3	☐4	☐5
f. I am confident in a doctor's ability to diagnose skin cancer.	☐1	☐2	☐3	☐4	☐5
g. I have made plans about when to examine my own skin.	☐1	☐2	☐3	☐4	☐5
h. I have made plans about where I will be when I examine my skin.	☐1	☐2	☐3	☐4	☐5
i. If I don't manage to examine my skin as planned I will find another opportunity.	☐1	☐2	☐3	☐4	☐5

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How You Feel

Please read each item and place a tick in the box beside the reply which comes closest to how you have been feeling **in the past week**. Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought-out response. **Please tick only one box in each section**

1. I feel tense or 'wound up':
- Most of the time ☐
- A lot of the time ☐
- Time to time, Occasionally ☐
- Not at all ☐

2. I feel as if I am slowed down:
- Nearly all the time ☐
- Very often ☐
- Sometimes ☐
- Not at all ☐

3. I still enjoy the things I used to enjoy:
- Definitely as much ☐
- Not quite as much ☐
- Only a little ☐
- Hardly at all ☐

4. I get a sort of frightened feeling like 'butterflies' in the stomach:
- Not at all ☐
- Occasionally ☐
- Quite often ☐
- Very often ☐

5. I get a sort of frightened feeling as if something awful is about to happen:
- Very definitely and quite badly ☐
- Yes, but not too badly ☐
- A little, but it doesn't worry me ☐
- Not at all ☐

6. I have lost interest in my appearance:
- Definitely ☐
- I don't take so much care as I should ☐
- I may not take quite as much care ☐
- I take just as much care as ever ☐

7. I can laugh and see the funny side of things:
- As much as I always could ☐
- Not quite so much now ☐
- Definitely not so much now ☐
- Not at all ☐

8. I feel restless as if I have to be on the move:
- Very much indeed ☐
- Quite a lot ☐
- Not very much ☐
- Not at all ☐

9. Worrying thoughts go through my mind:
- A great deal of the time ☐
- A lot of the time ☐
- From time to time but not too often ☐
- Only occasionally ☐

10. I look forward with enjoyment to things:
- As much as ever I did ☐
- Rather less than I used to ☐
- Definitely less than I used to ☐
- Hardly at all ☐

11. I feel cheerful:
- Not at all ☐
- Not often ☐
- Sometimes ☐
- Most of the time ☐

12. I get sudden feelings of panic:
- Very often indeed ☐
- Quite often ☐
- Not very often ☐
- Not at all ☐

13. I can sit at ease and feel relaxed:
- Definitely ☐
- Usually ☐
- Not often ☐
- Not at all ☐

14. I can enjoy a good book or radio or TV programme:
- Often ☐
- Sometimes ☐
- Not often ☐
- Very seldom ☐

Other Health Conditions

This section will cover questions about diseases and health conditions that you may already have or have had in the past.

27. Has a doctor ever told you that you have or have had any of the following conditions?

PLEASE TICK ALL THAT APPLY AND GIVE YOUR AGE AT FIRST DIAGNOSIS

	No [1]	Yes [2]	Age at first diagnosis	Don't know [3]
1. Heart Conditions (Heart Attack, Coronary, Myocardial Infarction, Angina Pectoris)				
2. High Blood Pressure/Hypertension				
3. High Cholesterol/Lipid Problems				
4. Stroke				
5. Diabetes/High Blood Sugar				
6. Lung Conditions (Asthma/Chronic Bronchitis/Emphysema Chronic Obstructive Lung Disease/COPD)				
7. Stomach or Duodenal Ulcer				
8. Chronic Headaches/Migraine				
9. Musculo-skeletal Disorders (Osteoporosis, Back Problems)				
10. Arthritis (Osteoarthritis/Rheumatoid Arthritis)/other joint complaints				

	No [1]	Yes [2]	Age at first diagnosis	Don't know [3]
11. Cancer/Leukaemia (excluding skin cancer)				
12. Problems with eye sight which could make it difficult to examine my own skin				
13. Mental health problems (Anxiety, Depression, Post-traumatic Stress Disorder)				
14. Problems with mobility which could make it difficult to examine my own skin				
15. Any other prolonged or serious illness? If yes, please specify below. _____				

Please list any medication, including over the counter medicines, that you are taking in the space below.

Personal Background

And finally …… some questions about yourself.

28. Are you

☐ 1 20-30

☐ 2 31-40

☐ 3 41-50

☐ 4 51-60

☐ 5 61-70

☐ 6 71-80

☐ 7 81-90

☐ 8 91 or older

29. Do you live?

☐ On your own

☐ With a partner/spouse

☐ With other family *(Please say who)* _____

☐ Other *(Please say who)* _____

30. How would you <u>best</u> describe your current work situation?

☐ 1 Employed full-time (include self-employed/business/farming)

☐ 2 Employed part-time or casual (include self-employed/business/farming)

☐ 3 Full-time home duties/home-carer

☐ 4 Student

☐ 5 Unemployed or looking for work

☐ 6 Retired

☐ 7 Permanently ill/unable to work

☐ 8 Other (please specify) ……

31. Is your main job or activity now…?

☐ 1 Mainly indoors

☐ 2 Mainly outdoors

☐ 3 About equal amounts indoors and outdoors

32. What is your present marital status?

☐ 1 Married/living together

☐ 2 Divorced/separated

☐ 3 Widowed

☐ 4 Single/never married

☐ 5 Other (please specify) ……

33. Approximately what is the distance from your home to your GP

☐ Minutes by car

☐ Miles

34. Do you: (Please tick one box only)

☐ Own your home

☐ Rent your home

☐ Other (Please state……..)

Thank you for helping us with this important research.

If you have any comments about any of the questions that we have asked, please add them here.

Thank you for completing this survey. Please return it using the reply-paid envelope provided (NO STAMP IS NEEDED)

514x386mm (180 x 180 DPI)

BMJ Open

Digitally supported total skin self-examination at home for people treated for cutaneous melanoma: developing and simulating experience of the ASICA intervention

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Digitally supported total skin self-examination at home for people treated for cutaneous melanoma: developing and simulating experience of the ASICA intervention.

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ABSTRACT

Objectives: To develop a digital intervention to prompt, support and respond to the outcomes of total skin self-examinations (TSSEs) at home by people treated for cutaneous melanoma.

Design: A complex intervention development study

Setting: Northeast Scotland

Participants: Semi-structured scoping interviews; People previously treated for cutaneous melanoma (n=21). Pilot testing; people treated for melanoma stages 0-2C (n=20); general practitioners (n=6); and a nurse specialist in dermatology (n=1).

Intervention: A tablet-based digital intervention designed to prompt and support TSSEs comprising instructional videos and electronic reporting (including photographs) to a clinical nurse specialist in dermatology with subsequent clinical triage.

Primary and secondary outcome measures: Qualitative assessment of intervention feasibility and acceptability and quantitative assessment of intentions and confidence to perform TSSEs in pilot participants.

Results: The majority of pilot participants were strongly positive and adhered well to the intervention (n=15) with seven of these reporting symptoms of concern at some point during the six month pilot. Four patients complied intermittently, three reporting skin problems at least once during the pilot, and one withdrew. Two patients underwent skin surgery as a result of participating in the pilot, with one proving to have a recurrent melanoma, the other a benign lesion. A number of practical issues to improve the usability of the intervention were identified. The proportion of participants reporting intention to check their skin at least monthly increased during the intervention as did confidence to conduct a skin check.

Conclusions: People previously treated for cutaneous melanoma are prepared to use digital technology to support them in conducting total skin self-examination. An intervention has

been developed which is practical, effective and safe and, after addressing minor practical issues, could now be evaluated for clinical outcomes in a randomised clinical trial.

ALTERNATIVE ABSTRACT

Objective: To develop a digital intervention to prompt, support and respond to the outcomes of total skin self-examinations (TSSEs) at home by people treated for cutaneous melanoma.

Methods: A four-stage iterative process guided by the MRC Framework. First, we used literature and patient interviews to explore technology in cancer follow-up, and if people with melanoma perceived technology could support them in TSSE. Second, in consultation with behavioural experts, we developed a theoretical model of our intervention. Third, we modelled the delivery of the combined components of the intervention using an experience laboratory where healthy volunteers simulated the processes of the theorized intervention. Fourth, we assessed the feasibility and acceptability of the prototype intervention through a pilot exercise with a group of patients supported by a nurse specialist in dermatology.

Results: Literature and interviews supported and informed the development of a theoretical intervention. A theoretical model, based on the IMB and underpinned by control theory, was successfully refined into a working prototype at the experience laboratory. It was then piloted with 19 volunteers previously treated for stage 0-2C cutaneous melanoma. Participants were strongly positive and most adhered well to the intervention (n=15) with seven reporting concerns. Four complied intermittently, three reporting skin problems at least once, and one withdrew. Two underwent skin surgery, with one proving to have recurrent melanoma, the other a benign lesion. Practical issues to improve the intervention were identified. The proportion of participants reporting intention to check their skin at least monthly increased during the intervention as did confidence to conduct a skin check.

Conclusions: People treated for cutaneous melanoma are prepared to use digital technology to support them in conducting TSSE. An intervention has been developed which is practical,

effective and safe. After addressing minor practical issues it should be evaluated in a randomised trial.

ARTICLE SUMMARY

Article focus: We describe the development and feasibility testing of a complex, digitally supported, behavioural intervention to prompt, support and respond to regular total skin self-examination by people previously treated for cutaneous melanoma.

Key messages: A feasible and acceptable intervention has been developed. Participants in the pilot study adhered well and were highly positive about their experience of using the intervention. Preliminary evidence suggests that the intervention can help sustain regular total skin self-examination by people previously treated for cutaneous melanoma and lead to prompter resolution of concerns, and potentially early detection of recurrence.

Strengths and limitations of this study:

- The study involved key stakeholders and followed a well-evidenced and iterative approach to developing theory, devising an intervention and establishing its feasibility and potential efficacy in a real-world clinical environment.
- The pilot is small-scale which has implications about the representativeness of our participants. A randomised clinical trial is now required to inform wider implementation.

INTRODUCTION

People previously treated for cutaneous melanoma are at risk of recurrences and new primary melanomas. The early detection of these events is one of the key aims of structured follow-up programmes for cutaneous melanoma and these are supported by guidelines in most countries.[1,2] Delivering effective structured melanoma follow-up to a growing population of eligible people is burdensome to health services, especially since many recurrences and new primaries occur in the intervals between structured melanoma follow-up visits.[1] In recognition of this, many experts advocate that patients treated for cutaneous melanoma should be instructed to perform total skin self-examinations (TSSESs) and to conduct these examinations regularly in the intervals between structured follow-up visits.[3]

There are reasons to believe that such regular TSSESs performed by people previously treated for cutaneous melanoma could yield marked survival benefits, for example, those who detect their own recurrences may have as much as a 63% reduction in mortality.[4,5,6] Furthermore, a review of the efficacy of skin self-examination for early detection of melanoma found evidence of high specificity (83% to 97%) for the detection of new lesions.[7] Sensitivity was lower but the included studies were not conducted with those previously treated for melanoma. It seems likely, although it cannot be stated with certainty, that a previous diagnosis of melanoma would increase knowledge and awareness with a corresponding increase in sensitivity. There is also some evidence, from a US case control trial and Australian modelling paper, that skin self-examination can reduce the development of advanced disease and facilitate early detection of recurrence by people affected by melanoma.[6,8] It is hoped that support to perform TSSEs could enable both recurrences and new primaries to be detected at an earliest stage when a cure may still be possible. The risk of recurrence in cutaneous melanoma is influenced by the stage of disease at

diagnosis.[8] Less intense follow-up regimens have been advocated for those with early stage disease at diagnosis (Stage IA, IB, IIA) and effective and sustained TSSEs could be particularly important in underpinning these.[8] Equally, however, since all patients treated for cutaneous melanoma are at risk of recurrence, effective TSSEs could be viewed as having a role as an adjunct in follow-up irrespective of clinical stage at diagnosis

Despite this, TSSEs education and practice appears suboptimal with 70% of American melanoma patients indicating that they have never been advised to do it.[9] We have found similar evidence of under preparation to conduct and performance of TSSEs in a UK population.[10]

Evidence from randomised trials suggests that people can be appropriately trained to conduct TSSEs.[11,12,13,14,15] However it is less clear whether TSSEs, once learned, can be sustained. Recent qualitative evidence suggests that the intention to conduct TSSEs wanes with time.[10] Digital technologies are becoming more prevalent in society, with a recent report that 49% of UK homes own at least one smartphone, tablet and computer.[16] More and more people are using personal electronic devices such as tablets and smartphones to obtain health information and to interact with healthcare providers.[17] This paper reports the development, pilot testing and preliminary evaluation of the Achieving Self-directed Integrated Cancer Aftercare (ASICA) intervention, a tablet computer based application designed to prompt and support total skin self-examination at home by people treated for cutaneous melanoma.

DEVELOPING A DIGITAL INTERVENTION – METHODS AND RESULTS

Overview

Our approach was based on the key development activities outlined in the MRC Framework for the development and evaluation of complex healthcare interventions.[18,19] Our approach comprised a number of activities which:

A) **Generated evidence** on how technology has been used in cancer follow-up, how people with melanoma perceived this technology that could be used to support them to conduct TSSEs, and how to target technology at those patients with most potential to benefit.

B) **Identified and developed theory** grounded in Information Motivation Behaviour Skills (IMB) as an explanatory model combined with Control Theory and Implementation Intentions to underpin the theoretical development of the intervention.[20,21,22,23,24]. The IMB model proposes three requisites for engaging in preventive behaviours: individuals must have access to relevant information; be motivated to act; and be both capable and confident (self-efficacious) enough to carry out the behaviour in question . IMB has been used successfully to explain and change health relevant, preventive behaviours; for example an IMB based intervention was more effective than information alone in increasing HIV prevention behaviour (condom use) in truck drivers. [20,25]Control theory, first proposed in 1982, proposes that behaviour is maintained through monitoring and evaluation of the discrepancy between goals and current behaviour via a discrepancy-reducing feedback loop.[22,26,27] A specific goal (e.g. performing TSSE) is compared with current behaviour and if a discrepancy is detected, action is taken to bring behaviour closer into line with the goal. If the behaviour gets closer to the goal in response to feedback, the behaviour persists but if the discrepancy is perceived to be too great the individual may disengage from the behaviour. Interventions based on Control Theory

are consistently shown to be effective in changing health related behaviours in clinical and non-clinical populations.[28] For example, in a meta-regression examining interventions to change health-related behaviours in 122 studies, the most effective interventions included techniques based on Control Theory (self-monitoring goal setting, specify action goals, feedback and review of goals).[29] A third model used in the current study concerns 'implementation intentions' or 'action plans'.[23,24] Action Plans are short 'if-then' plans that have been shown to be effective in enabling individuals to achieve their behavioural goals in a wide range of contexts. Thus IMB theory proposes the factors needed to engage in a target behaviour - information, motivation and skills/confidence, and Control Theory and Action Plans indicate the processes necessary to keep the behaviour going (goal prioritisation, feedback, behavioural discrepancy detection), and the techniques that can be used to help individuals achieve and maintain target behaviours. Using these models the components for a potential intervention were theorized in consultation with experts in behavioural science, and the mechanism for the whole intervention to prompt, record and respond to TSSEs by patients in their own homes was conceptualized and implemented using Behaviour Change Techniques (BCTs).

C) **Modelled the process** of delivery of the combined components of the intervention. A major challenge to this project was to combine the theory and evidence-based components into a viable intervention and we used innovative methods to simulate the full intervention. This was done using an experience laboratory event facilitated by experts where healthy volunteers simulated the processes of the theorized ASICA intervention.

D) **Assessed the feasibility and acceptability** of the prototype ASICA intervention (figure 1) through a pilot exercise with a group of patients supported by a nurse specialist in dermatology.

A) Generating the evidence to use and target technology

Evidence was derived from three sources. First, a systematic review was conducted to determine how technology has been used to support people with cancer. The methodology and results of this systematic review are reported in detail elsewhere.[30] Second, interviews were conducted with 21 people previously treated for cutaneous melanoma. The methodology and results of these interviews are reported in detail in a previous publication.[10] Third, clinical data were sought and obtained where available on recent recurrences and new primary melanomas diagnosed in Northeast of Scotland. The methods to obtain, analyse and interpret these data have been reported in detail.[3]

When integrated, this evidence suggests that the technology to deliver cancer follow up care remotely is available, safe and acceptable. Furthermore, people treated for cutaneous melanoma can see the benefit of conducting TSSEs but feel ill-equipped to perform it properly, safely, regularly and sustainedly. They can, however, see the potential of technology to support them in this endeavour and want to be shown how to conduct sequential TSSEs and then reminded when and how to do it. They also believe that this process could be supported by repeated reference to an instructional resource (e.g. a video) and self-reference (e.g. a digital skin map). Once they have conducted a TSSE they want to be able to report their findings quickly to a specialist and be reassured that the specialist would check their report and respond quickly if there were concerns. They would also welcome the potential opportunity to engage with healthcare professionals from their own homes without inconvenience (travel, time off work, parking). This was especially so for rural dwellers.

The evidence garnered from the literature and interviews also found that potential recipients strongly felt that approaches to monitor potential recurrence need to be developed carefully, and should not replace current hospital based follow-up until their safety and efficacy have been proven. The clinical data also suggested that recurrence is relatively common, occurs early and is usually found at the follow-up clinic within the first year. Therefore, an intervention to support TSSEs should be implemented within a month or so of diagnosis to afford maximum benefit.

B) Identifying and developing theory

The research team included an academic GP, a health services researcher, two health psychologists, and two computer scientists). Together, they had expertise in intervention development and evaluation, behaviour change and translating behavioural interventions into programmed computer applications. The chief investigator (an academic GP) first conceptualized the aims, processes and outcomes that the digital intervention should achieve. The final theoretical intervention was then produced in a series of three consensus meetings involving the whole research team.

The overriding aim of the intervention was to prompt the performance and reporting of good quality TSSEs by people previously treated for cutaneous melanoma. To achieve this, individuals must be shown how to use technology to conduct optimal TSSEs and then be prompted to conduct TSSEs regularly. They need to be able to remind themselves how to undertake TSSEs when they are due to do it. The intervention must then transmit the result of each patient's TSSEs to an overseeing clinician who will then respond appropriately (i.e. employ clinical triage) when a patient did identify a concern.

These aims, processes and outcomes were agreed at the first consensus meeting of the whole research team. Consideration was then given to the most appropriate theoretical model able to inform an intervention to achieve these aims, support the necessary processes and deliver the desired outcomes.

By consensus with the research team, it was decided that the Information-Motivation-Behaviour model offered the most promise in explaining current use of TSSEs.[20] Using this model the components for a potential intervention were theorized (i.e. components that would provide information about TSSEs, motivate individuals to perform TSSE and develop skills and confidence to perform TSSE) and the mechanism to prompt, record and respond to TSSEs by patients in their own homes was conceptualized. This is illustrated in figures 2a and 2b.[20,21]

At a second consensus meeting the results of the interviews conducted at stage A were considered. It was felt that, while the explanatory outline was based on the IMB, the results of interviews A indicated that, while patients required more information, they were already highly motivated and we therefore required a theory that guided the translation of motivation into action. The psychologists proposed that the process of the intervention should therefore incorporate Action Planning and should be revised to be additionally guided by 'Control Theory' as this theory deals with the process of self-regulation to change behaviour from a pattern that fails to achieve the person's goal to one that achieves their goal.[20,21,22] Together, these theories outline the process of change and give some guidance on the behaviour change techniques (BCTs) (i.e. the active ingredients that make up an intervention and are required to change behaviour) which the intervention required.[31] Some techniques were required to develop the knowledge and behavioural skills to enact the behaviour (e.g. demonstrating the behaviour, rehearsing/practising TSSEs), some to enhance/maintain the

person's motivation to engage in the process of TSSEs (e.g. providing information on health consequences of the behaviour (TSSEs), using a credible source for the information), some to enhance confidence that they could conduct TSSEs successfully (e.g. mastering the skills necessary), and some to enable self-regulation of action, especially remembering when to act (e.g. prompts and cues) and the sequence of actions necessary for the optimal clinical outcome (e.g. Action Planning, where patients who have decided to do TSSEs would make a clear plan when, where, and how they would do the examination). Planning 'how' to perform TSSE might include involving someone else (e.g. to examine areas of skin that they cannot easily see themselves), and planning 'when' to receive a reminder. In addition, some techniques were designed to maintain continued engagement in the behaviour (e.g. receiving feedback)[23,24].

To produce the final theoretical intervention a final consensus meeting was held. The whole research team first discussed the fidelity of the theory to the delivery of the intervention, and then worked together to map a theoretical structure for the intervention, incorporating the identified BCTs where appropriate. The intervention demonstrated the target behaviour (with a video clip); enhanced motivation to perform TSSE (with recorded information about the consequences of performing/not performing TSSE); enhanced confidence (with the incorporation of step by step instructions and opportunities to try each step into the video clip). The intervention tackled the issue of intentional and non-intentional non-adherence (including forgetting, deferring, avoidance or deciding it is unnecessary) (using cues to prompt individuals to undertake TSSEs); provided individuals with feedback about the behaviour (by sending TSSE results to health professionals and having the professional reply); and checked adherence to TSSE (by asking individuals to mark skin maps/record how long the personal skin check took). This gave an indication of thoroughness and provides information on those who do it more quickly because, for example, they have other

commitments, or those who choose to adopt avoidance. This allows the monitoring of adherence and engagement. A strategy to identify avoidance is very important since, without it, clinicians could be making clinical decisions and providing clinical advice based on incorrect information.

C) Modelling the process of delivery of the intervention

Experience Laboratory Event

An Experience Laboratory event was held in May 2013 at Glasgow School of Art's Centre for Design Innovation, in Forres, Moray.[32] This facility enables the creation of different environments to simulate real-life situations. The processes of delivery for the ASICA intervention, including simulation of the clinical sequences, were developed for use at the event. This included a simulation of the information and TSSEs demonstration for a potential supporting digital application, which was produced and embedded upon a hand-held tablet computer, with guidance from experts in design and presentation. Three locations were constructed: a patient bedroom **[Photo 1]**, a GPs surgery, and a clinical nurse specialist's office, the latter two being equipped with video-conferencing capability. The intervention components included in the simulation were: the cue to action (i.e. the prompt to complete TSSEs); the instructional video (showing how to conduct TSSEs); the skin-map (to be used while conducting TSSEs) and the report sent to health professionals (following completion of TSSEs).

The Experience Laboratory event was facilitated by design experts and attended by five patient volunteers (one supported by a helper) unaffected by cutaneous melanoma who performed a simulation of the theoretical intervention (as shown in figure 2b), a GP, a clinical nurse specialist in dermatology and the researchers.

Following an initial briefing session an existing instructional video produced by MASCOT (Melanoma Action and Support Scotland) describing how to conduct TSSEs was viewed by all participants. Two scenarios were constructed and enacted by each of the patient volunteers. In the first, the volunteers were asked to perform TSSEs at which no problems were detected. In the second scenario, the volunteers conducted TSSEs at which a new mole was detected. In this latter scenario the patient attended the GP surgery location for a video consultation between themselves and the co-located GP, and the remote clinical nurse specialist.

A professional TV company filmed and edited a video of the proceedings. At the conclusion of the day all participants viewed the video and a feedback and a debriefing session was held.

Integrating components and processes of the ASICA intervention

The Experience Laboratory enabled participating stakeholders to articulate and agree the benefits which the ASICA intervention could deliver to recipients. Furthermore, the activity enabled the theoretical components of the intervention to be operationalized in the simulation in order to gain insight into how well they integrated and served the purposes for which they were intended i.e. to support the mechanism of prompting, recording and enabling a response to TSSEs. The Experience Laboratory also enabled the researchers to gain insight into the detailed processes and the sequence in which they should occur to support the effective operation of the ASICA intervention. These were: the language used; training of the user; reporting to the specialist, and receiving feedback from the specialist. The detailed learning achieved on each component is also summarised in appendix 1.

Combining processes and components in a prototype intervention

As a result of the Experience Laboratory event, the detailed components and processes identified and developed during the theoretical stage were integrated into a prototype ASICA intervention, including a supporting digital application which was designed to run on a Google Nexus 7 tablet computer. Distinct from the application were several other components including:

1. The structured training session required at inception.

2. The initial and recurring cue to action required to remind the patient to conduct a personal skin check. The need for this to be a separate trigger (sent by email or text message to the recipient's mobile phone) was necessary to avoid the risk that the tablet was used only for skin checks with the risk that the prompt would not be received.

3. The specialist response, a telephone call from the overseeing specialist nurse within 24 hours, since both the human contact and immediacy were perceived as important reassuring factors when a patient could be anxious.

Based on the Experience Laboratory findings, the prototype intervention was adjusted for piloting. The need for clear and simple language unifying the application and supporting processes was perceived to be key to user engagement and intervention adherence. Within the digital application, language was made consistent with the language introduced at the training session. This was carried over into an animated instructional video which was produced and divided into chapters based upon body areas and used as a means to demonstrate and remind users about the specific behaviours required to check their body. Conducting the personal skin check using the application was designed to follow a logical sequence supported by a check-list for self-monitoring of completion. The process of feeling for lumps in regional nodal areas was routed so that only the appropriate nodal area was examined by each patient. Patients are also able to check an integrated individualized skin-map (formed of a series of

professionally produced clinical photographs of each patient) to determine whether skin lesions were new or changing. This function was further supported by the application storing previous reports/images for future reference. At the conclusion of the skin-check the ASICA application delivers a message that either no problem has been reported, or in the event that a symptom concern has been raised, that a specialist will be in touch within 48 hours with further advice. In either eventuality, the completion of the TSSEs is recorded and acknowledged giving a sense of completing the processes in a way that provides feedback and reassurance; this acts as a reward for completing the behaviour with the aim of reinforcing the behaviour so that individual patients will keep using the ASICA application.

D) Pilot study of the feasibility and acceptability of the prototype ASICA Intervention

The prototype ASICA intervention, including the supporting digital application, was subject to a pilot study of feasibility and acceptability amongst 20 people who had previously been treated for cutaneous melanoma.

Recruitment

Six practices were purposively selected to represent geographical spread within the NHS Grampian region of Scotland, and a GP from each was invited to a training meeting to have the protocol explained. The lead GP at each practice identified and approached potential participants for pilot study. Eligible patients were aged over 18, had been diagnosed and treated for cutaneous melanoma within the preceding five years, were currently receiving hospital-based follow-up, and had no nodal involvement or metastases (i.e. in-situ to stage 2C). The 20 people agreeing to participate were identified to, and approached by, the research team. The characteristics of participants are shown in table 1. Recruits attended the Medical Illustration department at the University of Aberdeen to have a full personal body mapping

digital photography taken. These were subsequently hosted on a secure server and could be accessed by individual patients to refer to during subsequent skin checks.

Participant Training

Three training sessions (each of two hours duration) were held in Aberdeen. The meetings followed a structured programme. Participants were introduced to the study and its purposes. The fact that the intervention was experimental (and additional) to their ongoing follow-up was stressed to ensure default from follow-up was not suggested. Participants were instructed in the use of the application and tablet, including how to access their digital skin maps, and their understanding and ability to comply checked. Patients were given detailed instruction manuals for both the tablet and the application. The project researcher arranged an individual meeting with one individual that was not able to attend the training sessions. To prepare for a future clinical trial a questionnaire was modified, with permission, from one used previously.[12,13,14] The questionnaire (included as appendix 2) sought information about respondents' skin cancer history, their skin self-examination practices and intentions, their attitudes, beliefs, self-efficacy and intentions about conducting skin self-examination, the Hospital Anxiety and Depression scale, information about comorbidities and their demographic characteristics. Participants were asked to complete the questionnaire upon arrival at their initial training session. They were then sent the questionnaire again at the conclusion of the pilot.

Process

Participants were sent a monthly email reminding them that it was time to conduct their personal skin check. Upon receipt of the reminder it was intended that they would use the ASICA application to help them systematically examine their skin and through the application they were able to view the integrated instructional video chapters to enable them

to do this. A structured electronic report pro-forma was available for completion. Where a new lesion was identified either at the previous melanoma site or a new one, participants were able to complete a free-text description and/or attach a photograph taken using the tablet's camera function. Completed reports were then sent electronically to a secure and remote server. The returned reports were communicated to, and reviewed by, an overseeing nurse specialist. Figure 1 illustrates the TSSEs procedure supported by the ASICA application. Where patients had identified concerns they were contacted by telephone within 24 hours by the reviewing nurse specialist who either provided reassurance or invited them to an upcoming clinic for subsequent review. At the conclusion of the pilot study all continuing participants were invited to attend for a total skin examination at their GP surgery and 15 accepted this invitation and attended. Three declined, one because he has regular private skin checks, one because he was on holiday at the time of the appointment, one because he was undergoing treatment for metastatic melanoma, and one did not attend.

At the conclusion of the pilot the project researcher SH contacted all participating patients and the overseeing clinical nurse specialist to conduct a brief telephone interview. These interviews aimed to capture the practical experiences and personal reflection of participants in the pilot study. They were conducted to identify participants' perceptions of strengths and weaknesses with the components, or the process and delivery of the intervention, so that subsequent improvements could be made. The interviews were guided by a topic schedule. Questions focused on patients' perceptions of the strengths and weakness of the ASICA application and how it had functioned. The interviewer also gathered information about how well the technical aspects of the intervention had worked from the nurse-specialist and patient perspective. The interviews were conducted by telephone and were recorded and transcribed for subsequent analysis and reflection by the research team.

As this was a pilot study no *apriori* hypotheses were determined based on clinical or psychological outcomes. We did, however, ask participants to complete a questionnaire seeking information about clinical, behavioural and psychological outcomes to aid preparation for a subsequent clinical trial.

Pilot Study Results

a) Feasibility

Details of the number and regularity of the skin checks participants performed during the pilot can be seen in table 2. Of the 20 participants, 15 complied well and eight reported no symptoms during the six-month pilot, seven reported at least one issue to the overseeing clinical nurse specialist. Most issues were resolved by submitting further images under the direction of the specialist nurse, with a corresponding telephone call. Two participants subsequently had the lesions spotted during personal skin checks removed, one was a recurrent melanoma and the other was a benign lesion. Of the three less compliant participants one regularly checked only his face where his original primary had been, another checked selected areas less regularly, citing work pressures and lack of time to conduct TSSEs. Another, a busy mum who stated she found it difficult to make time to conduct a TSSEs, checked their skin only once, on that occasion reporting three issues of concern to the overseeing nurse specialist. One participant withdrew for undisclosed personal reasons.

With respect to the technical operation of ASICA the nurse specialist stated that on the few occasions when photographs of new skin lesions had been submitted by participants these were typically of insufficient quality on which to base clinical judgements. However, in almost all cases he was able to contact the patient and direct them to take improved images. As a result guidelines to take good quality images have been incorporated into the revised app.

b) Acceptability

Patients were largely positive about their experience of using ASICA. The user-friendliness of ASICA was highlighted, along with views that participation supported good habits, allowed participants to become familiar with their own bodies, and provided them with empowerment and reassurance. Table 3 describes comments which reflect these themes. Technical issues raised by patients fell into three categories. There were minor issues with the interface (e.g parts of electronic buttons being obscured) which have been modified. Some patients, especially those in the more remote rural areas, were troubled by issues related to their internet connection. These are less easy to resolve but are likely to be more common in this particular geographical location than in the majority of the rest of the UK. Government initiatives and technological advances will help going forward in this regard. Similarly, there were some issues with the hardware, for example a malfunctioning charger in one case and a damaged screen in another.

c) Piloting trial procedures

Sixteen participants completed and returned the questionnaire at baseline and outcome. The data are not presented in detail. There were non-significant increases in the proportion of respondents indicating that they intended to check their skin at least monthly, and in the proportion indicating that they would be confident to perform total skin self-examination. No significant changes were observed between baseline and outcome in anxiety, depression or cancer worry. These data will however, be informative in determining power for a subsequent randomised trial.

DISCUSSION

Principal findings

The authors have developed a feasible clinical intervention process based on a digital tablet-based application to prompt, record, and respond to regular total skin self-examination by people previously treated for cutaneous melanoma. This has proven to be acceptable and safe for patients to use. There is also preliminary evidence that it can help reinforce and sustain TSSEs in a way that has not previously been possible. Further, there is some early evidence that it can bring new skin problems to medical attention sooner than would otherwise have been the case. It must also be noted however that the fact that a minority of patients did not comply, or complied only partially, indicates that ASICA will not compel all patients to conduct regular TSSEs or might require tailoring for some patients.

Strengths and limitations

Strengths

The approach adopted for developing the ASICA intervention had several inherent strengths. Developing interventions that employ digital technologies to deliver aspects of healthcare in a completely new way is immensely challenging. For this reason our approach benefited from employing the structured, iterative and well-rehearsed approach advocated by the MRC framework.[18,19] The use of the Experience Laboratory allowed simulation of the complete intervention, integrating components based on theory and evidence. The experience of the team in following this approach and the strong theoretical underpinning of the IMB and Control Theory models allowed the project to be phased and focused.[20,21] We involved key stakeholders – potential patients, clinicians, technology specialists, behaviour change intervention specialists, health service researchers – at each stage of the process so that their perspectives were identified and incorporated throughout. Furthermore, adopting this multidisciplinary approach enabled an ongoing understanding of the full spectrum of

potential challenges and caveats which the intervention was required to overcome, complemented by an ability to exploit the enablers perceived by each group. We were also able to ensure that we optimised the potential of the ASICA digital application, identifying the necessary processes and components, and ensuring that they were developed and embedded within the intervention in the most effective way.

Limitations

Some limitations must be acknowledged. The pilot was conducted on a small scale within Northeast Scotland. Clearly, this has implications about the representativeness of our participants. In terms of the whole Scottish population they were relatively affluent and also willing to learn about technology. It was assumed that all patients were physically capable of using the tablet and the application, but one could not use their fingers and required to be supplied with a stylus. There were other disabilities that were not provided for, for example poor eye-sight, lack of proficiency in English and restricted physical movement. A range of adherence was observed during the study and we were unable to understand this in detail. ASICA, as currently configured, will not suit everyone, but it may be possible to tailor it to individual need. While the developed intervention may have greater value and relevance among people familiar with technological advances and in localities where the clinical service is delivered to patients living remotely from the clinical centre, it is likely to have utility among a broad range of patients after melanoma diagnosis and treatment. This view is supported by noting that people with melanoma from stage 0-2C were willing to take part.

These limitations must be viewed against the backdrop of societal trends to embrace modern technology, and an increasing appetite amongst clinicians and policy makers to diagnose and manage skin cancer using digital means. A recent review, for example identified 40

applications of divergent quality and developmental rigour, for monitoring and diagnosis of pigmented skin lesions.[33]

Context with other studies

Where interventions have been specifically developed to improve TSSEs practice, and subjected to randomised trial the results have been disappointing, although the recruited patient groups have been different to this pilot study. Two randomised trials, one in a general US primary care population and another in Australian men over 50 at increased risk but with no previous melanoma, educated using brochure or video demonstrations only, reported increased TSSEs practice for 3-7 months, with participation returning to baseline after one-year.[11,12,13,14] A further study, employing a nurse or physician delivered an educational module supported by a personal skin map to US patients but referred to a secondary care pigmented lesion clinic, reported significant increases in TSSEs practice at 4 months.[15] Previous trials are informative to the current intervention for three reasons. First, all three were conducted in patients at increased risk, rather than patients actually treated for melanoma. It is therefore likely, that the target group of the ASICA intervention will be more motivated to conduct and sustain TSSEs than previously studied groups. Second, previous intervention development provides evidence that several of the components developed using health psychology-based approaches and incorporated into ASICA (such as the instructional videos, personal skin maps, cues to action and sample photographs) have the potential to promote and sustain, at least in the short-term, TSSEs in patients who form a lower risk group than the ASICA target population.[11,12,13,14,15] Third, and perhaps most importantly, the interventions previously trialled have comprised one-off educational activities with the issue of videos, booklets or brochures to patients for subsequent personal use.[11,12,13,14,15] ASICA, on the other hand, will use familiar everyday technology to prompt and sustain the

behaviour over time, in participant's own homes which should increase the likelihood of success.[34]

Lessons learned from this study

Evidence for components of previous interventions that have sustained TSSEs in the medium term has been translated onto a theoretical intervention based on well-evidenced theoretical models using the Behaviour Change Techniques Taxonomy v1 to implement the active behaviour change mechanisms.[35] We have learned that a skilfully facilitated experience laboratory can be used to provide rapid feedback on a theoretical and simulated intervention prior to its initial development and testing in a full-scale pilot trial. Finally, we have used carefully assembled theory and knowledge to build a working proto-type of an actual digital intervention to support TSSEs by people previously treated for cutaneous melanoma. This has functioned well in a real world pilot. It has succeeded in actually supporting, and responding to TSSEs, in a group of patients, who have appreciated and enjoyed using it. We have learned that it is a feasible and desirable intervention. We have also learned about the minor modifications that are required to proceed to a definitive clinical trial employing the ASICA intervention. Such a trial, conducted at several UK centres to ensure wider applicability, should now follow shortly, so that we can consolidate the promising findings reported here with definitive evidence of ASICA's role in future melanoma follow-up.

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CONTRIBUTORS

PM conceived the original intervention. SH conducted the initial exploratory interviews. The theoretical intervention was mapped by PM, SH, MJ, JA and translated into a working prototype by JM and MD, with advice on national implementation potential from FW. JM and MD developed the patient training sessions and materials, and the training was delivered by PM, JM, MD and SH. BB delivered the intervention. PM, SH, MD and FW generated and analysed the data. PM wrote the manuscript with contributions from all authors.

COMPETING INTERESTS

All authors have completed the Unified Competing Interest form at www.icmje.org/co_disclosure.pdf (available on request from the corresponding author) and declare that (1) None of the authors have support from any commercial company for the submitted work; (2) PM, JA, BB, MD, SH, JM, FW and MJ have no relationships with any commercial company that might have an interest in the submitted work in the previous 3 years (3) their spouses, partners or children have no financial relationships that may be relevant to the submitted work; and (4)) PM, JA, BB, MD, SH, JM, FW and MJ have no non-financial interests that may be relevant to the submitted work.

ETHICS APPROVAL

Full ethical approval for the interviews with people previously treated for melanoma study was granted by the North of Scotland Research Ethics Committee on 2nd May 2012. (REC reference number: 12/NS/0039). Full ethical approval for the pilot study was granted by the North of Scotland Research Ethics Committee on 10th June 2013. (REC reference number: 13/NS/0062)

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The University of Aberdeen is the study sponsor. PM, JA, MD, SH, JM and MJ are employees of the University of Aberdeen but all researchers were independent from the sponsor and funders in study design, the collection, analysis and interpretation of data, the writing of the article and the decision to submit for publication.

DATA SHARING STATEMENT

Process data about how ASICA performed during the pilot exercise and which does not identify patients, along with the technical specifications of the ASICA digital application may be available upon application to the corresponding author.

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Table 1: Characteristics of pilot study participants

ID	Age	Gender	Place of Residence*	Date of Mel Dx	Site	Stage
001	46	F	Accessible rural	2010	Arm	1.1mm Stage 1B
002	49	F	Other urban area	2012	Knee	0.5mm Stage 1A
003	72	F	Accessible rural	2013	Arm	0.4mm Stage 1A
004	69	M	Urban	2013	Breast	0.8mm Stage 1A
005	62	M	Remote rural	2012	Eyelid	M in situ Stage 0
006	66	F	Remote rural	2011	Cheek	0.3mm Stage 1A
007	72	M	Remote small town	2009	Cheek	2.8mm Stage 2A
008	70	M	Remote small town	2012	Shoulder	0.3mm Stage 1A
009*	41	F	Remote rural	2011	Back	>1mm
010	67	F	Accessible rural	2009	Arm	3mm Stage 2A
011	78	M	Remote small town	2008	Eyebrow	2.6mm Stage 2A
012	42	F	Accessible small town	2011	Back	M in situ Stage 0
013	75	F	Accessible rural	2009	Thigh	1.1mm Stage 2B
014	67	M	Accesible rural	2013	Shoulder	2mm Stage 2A
015	46	F	Accesible rural	2011	Abdomen	0.6mm Stage 1A
016	72	M	Accessible rural	2011	Forearm	1mm Stage 1B
017	65	M	Accessible rural	2014	Shoulder	M in situ Stage 0
018	69	M	Remote rural	2009	Shoulder	1.5mm Stage 1B
019	44	M	Accessible rural	2012	Abdomen	1.5mm Stage 1B
020	44	F	Accessible small town	2010	Lower leg	0.42mm Stage1A

Classifications from Scottish Government Urban-Rural Classification[36]

*Staging data were not available for this patient

Table 2: Compliance with intervention and outcome of monthly skin checks

Patient	Month 1 (May)		Month 2 (June)		Month 3 (July)		Month 4 (August)		Month 5 (September)		Month 6 (October)	
	Number of body areas checked	Changes reported	Number of body areas checked	Changes reported	Number of body areas checked	Changes reported	Number of body areas checked	Changes reported	Number of body areas checked s	Changes reported	Number of body areas checked	Changes reported
N=8: Complied well, reported no symptoms												
P02	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**
P03	**0**	**0**	**0**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**0**	**0**
P04	**5**	**0**	**5**	**0**	**5**	**0**	**0**	**0**	**0**	**0**	**5**	**0**
P05	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**
P06	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**
P10	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**
P16	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**
P19	**5**	**0**	**0**	**0**	**5**	**0**	**0**	**0**	**5**	**0**	**5**	**0**
N=7: Complied well, reported symptoms												
P01	**4**	**1**	**0**	**0**	**5**	**2**	**5**	**2**	**4**	**1**	**5**	**0**
P07	**5**	**3**	**5**	**5**	**5**	**2**	**5**	**0**	**5**	**2**	**5**	**0**
P08*	**4**	**0**	**5**	**0**	**5**	**0**	**5**	**2**	**5**	**0**	**5**	**1**
P13	**3**	**3**	**1**	**1**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**
P14	**0**	**0**	**3**	**2**	**4**	**0**	**5**	**1**	**5**	**0**	**4**	**0**
P15	**5**	**1**	**0**	**0**	**5**	**1**	**5**	**0**	**5**	**0**	**5**	**0**
P18* **	**5**	**1**	**0**	**0**	**5**	**0**	**0**	**0**	**5**	**1**	**0**	**0**
N= 3: Complied less well, reported symptoms												
P11**	**1**	**1**	**1**	**1**	**1**	**0**	**1**	**1**	**1**	**1**	**1**	**1**
P12	**0**	**0**	**1**	**0**	**0**	**0**	**3**	**1**	**0**	**0**	**0**	**0**
P17	**0**	**0**	**0**	**0**	**3**	**3**	**0**	**0**	**0**	**0**	**0**	**0**
N=1: Complied poorly, reported no issues (P20												
P20	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**5**	**0**	**0**	**0**
P09 PATIENT WITHDREW CITING PERSONAL CIRCUMSTANCES MAKING SKIN CHECKS DIFFICULT – NOT CLEAR WHAT THESE WERE												

*P8 diagnosed with recurrent melanoma after excision of lesion noticed during personal skin check

**P11 checked head and neck only

***P18 diagnosed with benign lesions on both legs after excision of lesions noticed during personal skin check

Table 3: Comments from patient interviews reflecting views on usability and acceptability

A USER FRIENDLY DEVICE P03 – "Yes, it was quite clear the actual information that we were given, very clear, beautifully set out, very easy to use and understand. P04 – "Very good. Very good indeed. It's very clear, easy to understand and useful in tips about parting your hair and getting somebody else to check the back of it for you and things like that, yeah, very clear and easy to understand and you know, tips about how to do awkward places on yourself, yes. P05 – "So what I've done is have a good look at myself over the preceding days, if you know what I mean, just as and when it was comfortable. And really handy, when I was getting changes, getting up or going to bed or what have you, in the shower. And then just rattle through the app. P08 – "The animations that were provided I thought were a really good guide, for somebody that's not used to technology it was really simple." P17 – "Well it tells you exactly what you need to know, there's no question about that." P21 – "The instructions were excellent, they were very well laid out. The videos were very helpful showing you exactly what you needed to do and how to check yourself all over."
ESTABLISHING GOOD HABITS P04 – "But the fact that it makes people do it once a month or whatever, it focuses the attention because it's something we'd probably be a bit slapdash with normally." P13 – "The tablet is great. Totally self-explanatory and the videos are very easy to watch and everything so it very easy to do and send off the report. Everything was great." P15 – "It made you really thorough about the skin check procedure. There was no way you could miss anything out. It was really good." P16 – "Yes, as I say, it's all clear and it's really good to see every part of your body…to go through it all in separate stages. Yes, it make you do it all in a through way, which is important, since I'm not getting checked at the hospital anymore, so it's really important that I've got to remember to check my whole body in case something appears."
GETTING TO KNOW MY OWN BODY P01 – "I like having the maps to look at because I've got a lot of moles but I have discovered there might be a blind spot on my arms where it's not really getting my arm – if you know what I mean? P15 – "Without this it becomes very difficult to remember if anything has changed very much since the last time you looked. This was really the first time I've ever looked really closely at my body, and I think to myself "goodness, I didn't realise I have that there before." And then I go back to the body map and – which is a salutary exercise in itself - and see "oh yes, it was there." I suppose it's getting to know your body much better." P17 – "I never used to think about it, but I know what to look for now. If I see something I know what it is, and what to do. Before, I never would have noticed." P21 – "The more I've done it over the period of months, the more that I've gotten used to where everything is on my body, where all the different moles are." P21 – "Before starting this project I probably wasn't really checking my skin that much at all, but since I've been doing this, it's been much more regular and I've been paying much more attention to it.
FEELING REASSURED AND EMPOWERED P09-"I'm very pleased with it, because it's helping me, you feel in control, that you are looking after yourself." P12 – "If somebody is checking it, that can get back to you really quickly, then off to the GP. Very re-assuring." P14 – "And because I was doing it so diligently, I felt good about that." P14 – "It a brilliant idea, especially for people who are a long way away, because you can do a really thorough check, and received professional reassurance without having to travel all the way to Aberdeen."

Figure 1: TSSEs Procedure as Supported by the ASICA application

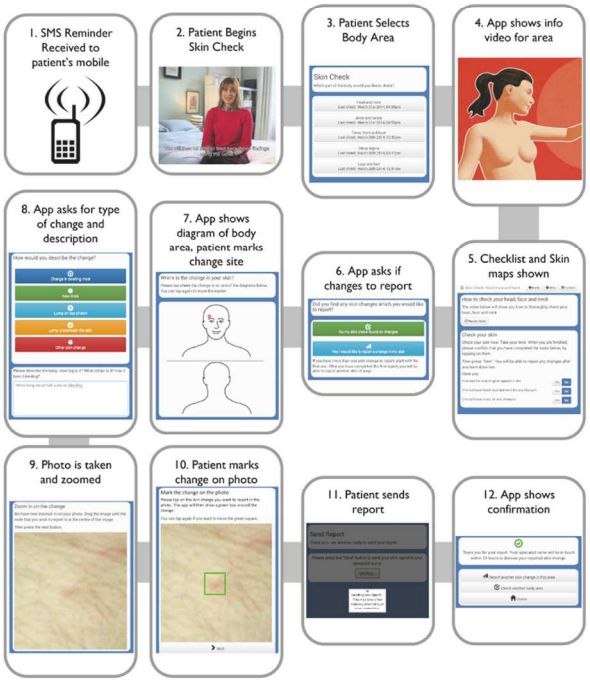

Figure 1
209x297mm (300 x 300 DPI)

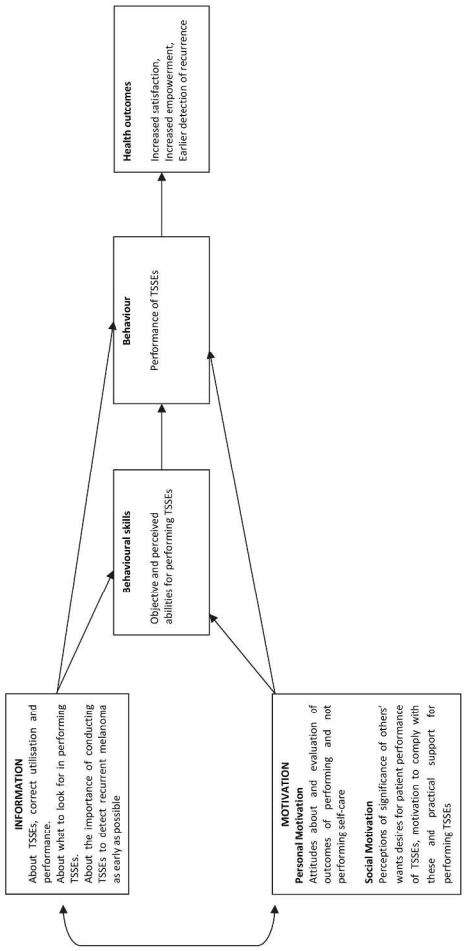

Figure 2a: Model demonstrating theoretical processes of ASICA according to Information-Motivation-Behaviour Skills (IMB) model – adapted from Cowling et al, 2011.

Figure 2a
209x297mm (300 x 300 DPI)

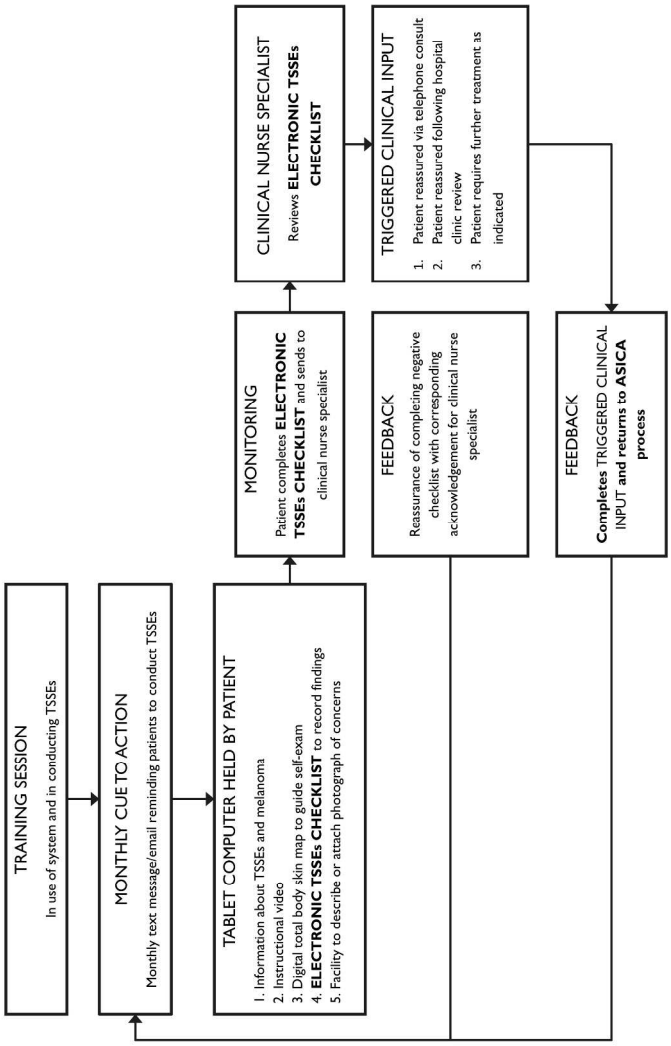

Figure 2b: Schematic demonstrating operationalization of components and processes of ASICA intervention adapted from Cowling et al, 2011.

Figure 2b
209x297mm (300 x 300 DPI)

Digitally supported total skin self-examination at home for people treated for cutaneous melanoma: developing and simulating experience of the ASICA intervention. Murchie et al

Appendix 1

This appendix displays the outcome questionnaire developed for use in a proposed future clinical trial of the ASICA intervention. It has been adapted, with permission from an instrument developed by Professor Monika Janda, Queensland University of Technology, Brisbane QLD, Australia. A related baseline questionnaire has also been prepared.

Janda M, Baade PD, Youl PH, Aitken JF, Whiteman DC, Gordon L, Neale RE. The skin awareness study: promoting thorough skin self-examination for skin cancer among men 50 years or older. Contemp Clin Trials 2009,31:119–130

Janda M, Neale RE, Youl P, Whiteman DC, Gordon L, Baade PD: Impact of video-based intervention to improve the prevalence of skin self-examinations in men 50 years or older: the randomized skin awareness trial. Arch Dermatol 2011, 147:799–806.

Janda M, Youl P, Neale R, Aitken J, Whiteman D, Gordon L, Baade P. Clinical Skin Examination Outcomes After a Video-Based Behavioral Intervention: Analysis From a Randomized Clinical Trial JAMA Dermatol. 2014;150(4):372-379. doi:10.1001/jamadermatol.2013.9313.

UNIVERSITY OF ABERDEEN

ASICA Questionnaire (Outcome)

Achieving Self-directed Integrated Cancer Aftercare

All the information that you provide in this questionnaire is confidential. You cannot be identified from any of the answers that you give.

If you have any questions regarding this questionnaire please contact:

For official use only

dot.rural
Transformation through Digital Innovation

Date returned	
Date entered	
Date checked	

What is the purpose of this

questionnaire?

The purpose of this questionnaire is to find out some things about you, your melanoma and your general health.

What if I am not sure how to answer some questions?

Do the best that you can.

Should you have any difficulties with completing the questionnaire, or have any questions about the study please contact:

How long will it take to complete?

It should take no longer than 20 minutes to complete.

Is the information confidential?

All the information that you give is extremely valuable to the study and is treated in the strictest confidence.

What should I do with my completed questionnaire?

After you have filled in the questionnaire please put it in the addressed FREEPOST envelope provided and post it back to us. NO POSTAGE STAMP IS REQUIRED

We would be very grateful if you could return your completed questionnaire as soon as possible.

Thank you

Skin Cancer History

1. Have you ever had a skin cancer, mole, or other spot/s removed or treated?

☐ 1 Yes

☐ 2 No → Go to Q4

☐ 3 Unsure/Don't Know → Go to Q4

2. How many skin cancers, moles, or other spots have you had treated?

☐ 1 One

☐ 2 Two to five

☐ 3 Six to ten

☐ 4 Eleven to twenty

☐ 5 Twenty-One to fifty

☐ 6 More than fifty

3. How old were you when you had your first skin cancer, mole, or other spot treated?

☐ Do not remember

☐ Years old

4. Are you currently concerned about a spot or mole?

☐ 1 Yes ☐ 2 No ☐ 3 Not sure

5. How likely is it, do you think, that you will get skin cancer again at some time in the future?

☐ 1 Not at all likely

☐ 2 Somewhat likely

☐ 3 Very likely

☐ 4 Don't know/not sure

Skin Self Examination

6. **Have you or someone who is not a doctor or nurse, such as your spouse or partner, ever deliberately checked any part of your skin for early signs of skin cancer.**

☐ 1 Yes ☐ 2 No → Go to Q13

☐ 3 Don't know → Go to Q13

7. **In the past 12 months, have you or someone who is not a doctor or nurse , such as your spouse or partner, deliberately checked any part of your skin for early signs of skin cancer.**

☐ 1 Yes ☐ 2 No → Go to Q13

☐ 3 Don't know

8. **In the past 12 months, how often have you or someone who is not a doctor or nurse checked any part of your skin for early signs of skin cancer?**

☐ 1 One to two times ☐ 3 Five to six times

☐ 2 Three to four times ☐ 4 More than six times

9. **In the past 6 months, how often have you or someone who is not a doctor or nurse checked any part of your skin for early signs of skin cancer?**

☐ 1 One to two times ☐ 3 Five to six times

☐ 2 Three to four times ☐ 4 More than six times

☐ 5 Zero

10. **Thinking back to the last time you or someone who is not a doctor or nurse checked your own skin, which areas of your body did you actually check?**

☐ 1 Face ☐ 8 Feet

☐ 2 Neck ☐ 9 Back of thighs/knees/shins

☐ 3 Upper Chest ☐ 10 Bottom

☐ 4 Arms ☐ 11 Lower Back

☐ 5 Hands ☐ 12 Higher Back

☐ 6 Torso ☐ 13 Back of Neck/Scalp

☐ 7 Front of thighs/knees/shins ☐ 14 Whole Body

11. During your last check, did you use a handheld mirror or full-size mirror to check difficult to see areas of your skin such as your back?

☐ 1 Yes, hand-held mirror ☐ 4 No

☐ 2 Yes, full-size mirror ☐ 5 Don't know

☐ 3 Yes, both

12. During your last check did you have someone to help you see difficult to see areas for example your wife, partner or another relative?

☐ 1 Yes ☐ 2 No ☐ 3 Don't know

13. In the next 12 months, how many times do you intend to check your skin for early signs of skin cancer?

☐ Please write the number in the box.

We would now like to know *how confident* you are about being able to check your skin. Please *circle the number* that best describes your level of confidence for each of the following four questions.

14. How confident are you that you can check your own skin correctly?

1	2	3	4	5	6	7	8	9	10
Not at all Confident				Moderately Confident					Highly Confident

15. How confident are you that you will find the time in the next 12 months to check your own skin.

1	2	3	4	5	6	7	8	9	10
Not at all Confident				Moderately Confident					Highly Confident

16. How confident are you that you will remember to check your own skin at least once a month.

1	2	3	4	5	6	7	8	9	10
Not at all Confident				Moderately Confident					Highly Confident

17. How confident are you that if you find a spot or mole of concern that you will take appropriate action.

1	2	3	4	5	6	7	8	9	10
Not at all Confident				Moderately Confident					Highly Confident

18. When you last checked your own skin, did you find a spot or mole of concern?

☐ 1 Yes → → Go to Q19

☐ 2 No → → Go to Q21

☐ 3 Don't know/unsure → Go to Q21

☐ 3 Did not check my skin → Go to Q21

19. If yes, what did you do?

☐ 1 Watched it for up to one month

☐ 2 Watched it for longer than one month

☐ 3 Showed it to partner/relative

☐ 4 Showed it to a doctor/nurse

☐ 5 Other, please specify ……

20. Over the next six months if you find a spot or mole that you are worried about what will you do?

You may tick one or more options

☐ 1 Show it to a partner, relative or friend

Would you do this:

☐ 1 Immediately

☐ 2 Within a few days

☐ 3 Within a week

☐ 4 Within a month

☐ 5 Other, please specify

☐ 2 Make an appointment with a doctor

Would you do this:

☐ 1 Immediately

☐ 2 Within a few days

☐ 3 Within a week

☐ 4 Within a month

☐ 5 Other, please specify

☐ 3 Contact the specialist nurse

Would you do this:

☐ 1 Immediately

☐ 2 Within a few days

☐ 3 Within a week

☐ 4 Within a month

☐ 5 Other, please specify

☐ 4 Watch it until the next prompt from the ASICA tablet arrives

☐ 5 Watch and wait

☐ 6 Other, please specify .....

Health Professional Skin Examination

21. Has a doctor or nurse ever deliberately checked any part of your skin for early signs of skin cancer since you received the ASICA electronic tablet?

☐ 1 Yes → Go to Q22

☐ 2 No → Go to Q26

☐ 3 Don't know → Go to Q26

22. In the past 12 months, has a doctor or nurse deliberately checked any part of your skin for early signs of skin cancer?

☐ 1 Yes → Go to Q23

☐ 2 No → Go to Q26

☐ 3 Don't know → Go to Q26

23. In the past 12 months has a doctor or nurse deliberately checked the skin on your whole body? Usually this would involve taking your clothes off at least down to your underwear.

☐ 1 Yes

☐ 2 No

☐ 3 Don't know

24. During your last skin check did the doctor suggest you check your own skin for early signs of skin cancer?

☐ 1 Yes ☐ 2 No

25. Did the doctor show you how to check your own skin for early signs of skin cancer?

☐ 1 Yes ☐ 2 No

Attitudes and Beliefs

For this section of the questionnaire we would like to find out what you think about checking your skin.

26. For each of the following statements please indicate whether you strongly disagree, disagree, agree, strongly agree, or are unsure with each statement. ***Please select only one option for each question.***

	Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree
a. It is important to check my skin for skin cancer even if I have no symptoms	☐1	☐2	☐3	☐4	☐5
b. Checking my skin would make me anxious.	☐1	☐2	☐3	☐4	☐5
c. Checking my skin regularly is a priority for me.	☐1	☐2	☐3	☐4	☐5
d. I could find something suspicious on my skin if it was there.	☐1	☐2	☐3	☐4	☐5
e. If I saw something suspicious on my skin, I'd go to the doctor straight away.	☐1	☐2	☐3	☐4	☐5
f. I am confident in a doctor's ability to diagnose skin cancer.	☐1	☐2	☐3	☐4	☐5
g. I have made plans about when to examine my own skin.	☐1	☐2	☐3	☐4	☐5
h. I have made plans about where I will be when I examine my skin.	☐1	☐2	☐3	☐4	☐5
i. If I don't manage to examine my skin as planned I will find another opportunity.	☐1	☐2	☐3	☐4	☐5

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How You Feel

Please read each item and place a tick in the box beside the reply which comes closest to how you have been feeling **in the past week**. Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought-out response. **Please tick only one box in each section**

1. I feel tense or 'wound up':
- Most of the time ☐
- A lot of the time ☐
- Time to time, Occasionally ☐
- Not at all ☐

2. I feel as if I am slowed down:
- Nearly all the time ☐
- Very often ☐
- Sometimes ☐
- Not at all ☐

3. I still enjoy the things I used to enjoy:
- Definitely as much ☐
- Not quite as much ☐
- Only a little ☐
- Hardly at all ☐

4. I get a sort of frightened feeling like 'butterflies' in the stomach:
- Not at all ☐
- Occasionally ☐
- Quite often ☐
- Very often ☐

5. I get a sort of frightened feeling as if something awful is about to happen:
- Very definitely and quite badly ☐
- Yes, but not too badly ☐
- A little, but it doesn't worry me ☐
- Not at all ☐

6. I have lost interest in my appearance:
- Definitely ☐
- I don't take so much care as I should ☐
- I may not take quite as much care ☐
- I take just as much care as ever ☐

7. I can laugh and see the funny side of things:
- As much as I always could ☐
- Not quite so much now ☐
- Definitely not so much now ☐
- Not at all ☐

8. I feel restless as if I have to be on the move:
- Very much indeed ☐
- Quite a lot ☐
- Not very much ☐
- Not at all ☐

9. Worrying thoughts go through my mind:
- A great deal of the time ☐
- A lot of the time ☐
- From time to time but not too often ☐
- Only occasionally ☐

10. I look forward with enjoyment to things:
- As much as ever I did ☐
- Rather less than I used to ☐
- Definitely less than I used to ☐
- Hardly at all ☐

11. I feel cheerful:
- Not at all ☐
- Not often ☐
- Sometimes ☐
- Most of the time ☐

12. I get sudden feelings of panic:
- Very often indeed ☐
- Quite often ☐
- Not very often ☐
- Not at all ☐

13. I can sit at ease and feel relaxed:
- Definitely ☐
- Usually ☐
- Not often ☐
- Not at all ☐

14. I can enjoy a good book or radio or TV programme:
- Often ☐
- Sometimes ☐
- Not often ☐
- Very seldom ☐

Other Health Conditions

This section will cover questions about diseases and health conditions that you may already have or have had in the past.

27. Has a doctor ever told you that you have or have had any of the following conditions?

PLEASE TICK ALL THAT APPLY AND GIVE YOUR AGE AT FIRST DIAGNOSIS

	No [1]	Yes [2]	Age at first diagnosis	Don't know [3]
1. Heart Conditions (Heart Attack, Coronary, Myocardial Infarction, Angina Pectoris)				
2. High Blood Pressure/Hypertension				
3. High Cholesterol/Lipid Problems				
4. Stroke				
5. Diabetes/High Blood Sugar				
6. Lung Conditions (Asthma/Chronic Bronchitis/Emphysema Chronic Obstructive Lung Disease/COPD)				
7. Stomach or Duodenal Ulcer				
8. Chronic Headaches/Migraine				
9. Musculo-skeletal Disorders (Osteoporosis, Back Problems)				
10. Arthritis (Osteoarthritis/Rheumatoid Arthritis)/other joint complaints				

	No [1]	Yes [2]	Age at first diagnosis	Don't know [3]
11. Cancer/Leukaemia (excluding skin cancer)				
12. Problems with eye sight which could make it difficult to examine my own skin				
13. Mental health problems (Anxiety, Depression, Post-traumatic Stress Disorder)				
14. Problems with mobility which could make it difficult to examine my own skin				
15. Any other prolonged or serious illness? If yes, please specify below. _____				

Please list any medication, including over the counter medicines, that you are taking in the space below.

Personal Background

And finally …… some questions about yourself.

28. Are you

☐ 1 20-30

☐ 2 31-40

☐ 3 41-50

☐ 4 51-60

☐ 5 61-70

☐ 6 71-80

☐ 7 81-90

☐ 8 91 or older

29. Do you live?

☐ On your own

☐ With a partner/spouse

☐ With other family *(Please say who)* _____

☐ Other *(Please say who)* _____

30. How would you <u>best</u> describe your current work situation?

☐ 1 Employed full-time (include self-employed/business/farming)

☐ 2 Employed part-time or casual (include self-employed/business/farming)

☐ 3 Full-time home duties/home-carer

☐ 4 Student

☐ 5 Unemployed or looking for work

☐ 6 Retired

☐ 7 Permanently ill/unable to work

☐ 8 Other (please specify) ……

31. Is your main job or activity now…?

☐ 1 Mainly indoors

☐ 2 Mainly outdoors

☐ 3 About equal amounts indoors and outdoors

32. What is your present marital status?

☐ 1 Married/living together

☐ 2 Divorced/separated

☐ 3 Widowed

☐ 4 Single/never married

☐ 5 Other (please specify) ……

33. Approximately what is the distance from your home to your GP

☐ Minutes by car

☐ Miles

34. Do you: (Please tick one box only)

☐ Own your home

☐ Rent your home

☐ Other (Please state……..)

Thank you for helping us with this important research.

If you have any comments about any of the questions that we have asked, please add them here.

Thank you for completing this survey. Please return it using the reply-paid envelope provided (NO STAMP IS NEEDED)

Digitally supported total skin self-examination at home for people treated for cutaneous melanoma: developing and simulating experience of the ASICA intervention. Murchie et al

APPENDIX 2: Experience lab outcomes

BENEFITS – "WHAT DO I GET FROM THIS?": Developing motivation to engage with ASICA and TSSE

Patient volunteers perceived the following advantages of the ASICA intervention: reduced travel and time; having your own skin map (an aide memoire and evidence if needed); speed and simplicity of the process; rapid reassurance when concerned; raised awareness of caring for my skin and empowerment; feels like the medical staff care for me; secure and I can trust the NHS with my information.

COMPONENTS – "NUTS AND BOLTS TO MAKE IT WORK": Action plans to enable TSSE and maintenance of use of ASICA

THE CUE TO ACTION

The email reminder should be sent at the right time – no point sending it on a Friday evening when the patient will be unable to get a response until the following Monday. It seems sensible, therefore, that these would be sent at the beginning of a week. It was also viewed as sensible to send this to another device/using another mechanism to get round the risk that the tablet may be stored in a drawer between skin-checks.

THE INSTRUCTIONAL VIDEO

The video to be embedded within ASICA had the following aims:

- To introduce self-monitoring
- To incentivise a personal skin check
- To provide persuasion from a credible source
- To provide behavioural instruction
- To demonstrate the required behaviour
- To provide information about health consequences

Comments on the existing video were generally negative. It was described as too long and repetitive and in need of "spicing up." However at least two of the patient volunteers warned that it needed to continue to be comprehensive.

Particular issues for improvement of the video were:

Provide incentive: There was nothing on the video that suggested participants might expect a better outcome by doing a personal skin check. This incentive does not have to be much – it could just be 'By doing this you will get early attention to any problems which the clinic can then deal with' You don't have to say you will save their lives.

Provide Information: Tell us why we are doing this and what we are looking for at each stage. Give us some information about moles (e.g. where are they most likely to be found). Tell us specifically what the things we are worried about look/feel like. Tell us how long the examination will take.

Have an inspiring voice over: The lady on the video was felt to be monotonous.

Make the background less gloomy: The dark background made the video seem oppressive.

Make the video less repetitive: Basic techniques should be explained once, i.e. examining skin and feeling for lumps.

Tailor the video: Give a video of a man for men and a woman for women.

Idealised body: Participants generally felt that a model with an "ideal" body was preferable to more realistic appearance.

Presence of moles: The model should have some moles. We should see them examining the moles as we would want them to do in the behaviour. We should also see how the patient would record this information within the intervention. This should be re-emphasis in each section of the video (i.e. after "The scalp" "The head" "The back".)

Use "point of view" perspective: To differentiate parts of the video where you are looking versus feeling. The video should make it clear that "Looking" and "Feeling" are two very different behaviours. This means that the video should emphasise both behaviours. The video should clearly distinguish between "looking" and "feeling." The video should show what people might see when they "look." Similarly, they should be shown how to "feel". This needs to be tailored to parts of the body – i.e. what are the hands doing when the patient is feeling the back of their legs. Video needs to introduce elements of how to feel for lumps, emphasising those that are practically shown at the training day.

Helpers: The EP day made it clear that people are going to be challenged to examine their back and their scalp. It might be good for the video to introduce the idea of "helpers" and a range of whom these might be – e.g. friends, spouse, carers, parents, children, GPs. It would then be good practice to ask the patients to identify an appropriate helper, a person whom they would most like to involve at recruitment. Perhaps a solution needs to be found for those that can't identify a helper.

Make the video interactive: Split into sections (e.g. head and neck, arms, legs) so that participants can tailor how they do the examination. It will also be important to structure it this way to facilitate a sequence, so that people can tick sections as they go along. The video, therefore, needs to be structured with reference to the check list which will be on the tablet. We should consider having a separate checklist for each part of the body. There is a need, however, to guard against making the system too complicated.

Consequently a new animated video was professionally produced for incorporation onto the tablet.

THE SKIN MAP

What are the technology options for this? Does it need to be broken down or could it be presented as a whole body or video map. It is likely that patients will need to visit Aberdeen for this to be done. Some of Susan's findings from the interviews suggest that this aspect of the project will need to be handled sensitively, one patient reported that having the skin map formed was a humiliating experience. Patients suggested that they wanted to be able to mark any concerns directly on their skin maps. They wanted to able to zoom in to see the detail of the skin map and also to be able to move the photo around, i.e. to see the next body part using the touch screen.

Digitally supported total skin self-examination at home for people treated for cutaneous melanoma: developing and simulating experience of the ASICA intervention. Murchie et al

In consequence arrangements were made at Medical Illustration at University of Aberdeen for each patient to have digital skin map images taken. These were subsequently incorporated onto individual Google Tablets for individual patients.

THE REPORT FORM

The report back form should include options for labelling and a free-text box to explain the outcome, e.g. new mole, new spot, lump, no concerns etc. Patients preferred not to have the option to mark the report urgent – felt that this is something for specialists to decide. Previous report backs should be stored within the app for future reference

PROCESSES – "FLOWS OF INFORMATION"

LANGUAGE

Language used throughout should be chosen with care. In particular, when asking people to perform tasks language should be simple. For example, the term "Personal Skin Check" was perceived as more meaningful, understanding and less daunting to an individual than "Total Skin Self-Examination." Language needs to communicate what they are being asked to do; why they are being asked to do it; how to do it; what might happen when they do it; what the corresponding consequences and further actions of outcomes is.

TRAINING THE USER

Training eventual participants in the pilot exercise will be key.

The issue of engaging participants with the technology is important. The consensus from the plenary was that patients would be more likely to embrace the use of the technology if it was presented in conjunction with the benefits of using technology and the incentives listed about. (e.g. less travel, more control etc). It will also make sense to introduce the technology used as "just something used in healthcare." Patients can manage many much more complex activities and equipment than are being proposed here, for example nebulisers, home oxygen and glucose monitoring in diabetes.

The training must, however, show people how to do the intervention. As one specialist has pointed out one of the main purposes of follow-up appointments is to detect nodal disease. For this reason the individual participants should be shown how to examine their appropriate lymph node basins (neck, groins or axilla. These are practical skills that need to be demonstrated and can be reiterated on the video

However, it will be important not to make the assumption that people will manage to use the tablet/technology. Appropriate training will, and should be delivered. It will also be important to recognise that younger people may be more easily able to engage with the technology. Nevertheless there is a danger of making assumptions according to age stereotypes. We should aim for a standardised non-ageist way of introducing the technology and training people in the system. We should guard against training which is patronising and offensive to older people and too sketchy for younger patients leaving them less well informed.

REPORTING TO THE SPECIALIST

Several functions of the intervention are encapsulated within this step. In most cases patients will be feeding back negative findings. This will convey a sense of reassurance to them and

will, in effect, be the reward for performing the behaviour. In other circumstances a new lesion will be found. In this case, a decision on what is to happen will be available within 48 hours, much quicker than under existing systems. It is likely, therefore that both outcomes will reinforce the behaviour.

There were few concerns from patients about communicating information (including body images remotely). They would assume that security was in place. Technology experts offered "scrambling", "encryption and "cropping images" as further means to ensure security.

FEEDBACK FROM THE SPECIALIST

When the report (no concern) or issue arising is returned participants would want to receive a "report received" receipt. They felt this should be tailored to reflect how long it would take to get a response. It should also provide a phone number which could be contacted if the patient was concerned meantime.

514x386mm (180 x 180 DPI)

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Digitally supported total skin self-examination at home for people treated for cutaneous melanoma: developing and simulating experience of the ASICA intervention

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Digitally supported total skin self-examination at home for people treated for cutaneous melanoma: developing and simulating experience of the ASICA intervention.

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ABSTRACT

Objectives: To develop a digital intervention to prompt, support and respond to the outcomes of total skin self-examinations (TSSEs) at home by people treated for cutaneous melanoma.

Design: A complex intervention development study

Setting: Northeast Scotland

Participants: Semi-structured scoping interviews; People previously treated for cutaneous melanoma (n=21). Pilot testing; people treated for melanoma stages 0-2C (n=20); general practitioners (n=6); and a nurse specialist in dermatology (n=1).

Intervention: A tablet-based digital intervention designed to prompt and support TSSEs comprising instructional videos and electronic reporting (including photographs) to a clinical nurse specialist in dermatology with subsequent clinical triage.

Primary and secondary outcome measures: Qualitative assessment of intervention feasibility and acceptability and quantitative assessment of intentions and confidence to perform TSSEs in pilot participants.

Results: The majority of pilot participants were strongly positive and adhered well to the intervention (n=15) with seven of these reporting symptoms of concern at some point during the six month pilot. Four patients complied intermittently, three reporting skin problems at least once during the pilot, and one withdrew. Two patients underwent skin surgery as a result of participating in the pilot, with one proving to have a recurrent melanoma, the other a benign lesion. A number of practical issues to improve the usability of the intervention were identified. The proportion of participants reporting intention to check their skin at least monthly increased during the intervention as did confidence to conduct a skin check.

Conclusions: People previously treated for cutaneous melanoma are prepared to use digital technology to support them in conducting total skin self-examination. An intervention has been developed which is practical, effective and safe and, after addressing minor practical issues, could now be evaluated for clinical outcomes in a randomised clinical trial.

ALTERNATIVE ABSTRACT

Objective: To develop a digital intervention to prompt, support and respond to the outcomes of total skin self-examinations (TSSEs) at home by people treated for cutaneous melanoma.

Methods: A four-stage iterative process guided by the MRC Framework. First, we used literature and patient interviews to explore technology in cancer follow-up, and if people with melanoma perceived technology could support them in TSSE. Second, in consultation with behavioural experts, we developed a theoretical model of our intervention. Third, we modelled the delivery of the combined components of the intervention using an experience laboratory where healthy volunteers simulated the processes of the theorized intervention. Fourth, we assessed the feasibility and acceptability of the prototype intervention through a pilot exercise with a group of patients supported by a nurse specialist in dermatology.

Results: Literature and interviews supported and informed the development of a theoretical intervention. A theoretical model, based on the IMB and underpinned by control theory, was successfully refined into a working prototype at the experience laboratory. It was then piloted with 19 volunteers previously treated for stage 0-2C cutaneous melanoma. Participants were strongly positive and most adhered well to the intervention (n=15) with seven reporting concerns. Four complied intermittently, three reporting skin problems at least once, and one withdrew. Two underwent skin surgery, with one proving to have recurrent melanoma, the other a benign lesion. Practical issues to improve the intervention were identified. The proportion of participants reporting intention to check their skin at least monthly increased during the intervention as did confidence to conduct a skin check.

Conclusions: People treated for cutaneous melanoma are prepared to use digital technology to support them in conducting TSSE. An intervention has been developed which is practical, effective and safe. After addressing minor practical issues it should be evaluated in a randomised trial.

ARTICLE SUMMARY

Article focus: We describe the development and feasibility testing of a complex, digitally supported, behavioural intervention to prompt, support and respond to regular total skin self-examination by people previously treated for cutaneous melanoma.

Key messages: A feasible and acceptable intervention has been developed. Participants in the pilot study adhered well and were highly positive about their experience of using the intervention. Preliminary evidence suggests that the intervention can help sustain regular total skin self-examination by people previously treated for cutaneous melanoma and lead to prompter resolution of concerns, and potentially early detection of recurrence.

Strengths and limitations of this study:

- The study involved key stakeholders and followed a well-evidenced and iterative approach to developing theory, devising an intervention and establishing its feasibility and potential efficacy in a real-world clinical environment.
- The pilot is small-scale which has implications about the representativeness of our participants. A randomised clinical trial is now required to inform wider implementation.

INTRODUCTION

People previously treated for cutaneous melanoma are at risk of recurrences and new primary melanomas.[1,2] The early detection of these events is one of the key aims of structured follow-up programmes for cutaneous melanoma and these are supported by guidelines in most countries.[1,3,4] Delivering effective structured melanoma follow-up to a growing population of eligible people is burdensome to health services.[5] Furthermore, many recurrences and new primaries occur in the intervals between structured melanoma follow-up visits.[1,6] In recognition of this, guidelines advocate that patients treated for cutaneous melanoma should be instructed to perform total skin self-examinations (TSSESs) and to conduct these examinations regularly in the intervals between structured follow-up visits.[1,4]

There are reasons to believe that such regular TSSESs performed by people previously treated for cutaneous melanoma could yield marked survival benefits.[7,8] For example, those who detect their own recurrences may have as much as a 63% reduction in mortality.[9] Furthermore, a review of the efficacy of skin self-examination for early detection of melanoma found evidence of high specificity (83% to 97%) for the detection of new lesions.[10] Sensitivity was lower but the included studies were not conducted with those previously treated for melanoma. It seems likely, although it cannot be stated with certainty, that a previous diagnosis of melanoma would increase knowledge and awareness with a corresponding increase in sensitivity. There is also some evidence, from a US case control trial and Australian modelling paper, that skin self-examination can reduce the development of advanced disease and facilitate early detection of recurrence by people affected by melanoma.[9,11] It is hoped that support to perform TSSEs could enable both recurrences and new primaries to be detected at an earliest stage when a cure may still be possible. The risk of recurrence in cutaneous melanoma is influenced by the stage of disease at

diagnosis.[11] Less intense follow-up regimens have been advocated for those with early stage disease at diagnosis (Stage IA, IB, IIA) and effective and sustained TSSEs could be particularly important in underpinning these.[11] Equally, however, since all patients treated for cutaneous melanoma are at risk of recurrence, effective TSSEs could be viewed as having a role as an adjunct in follow-up irrespective of clinical stage at diagnosis

Despite this, TSSEs education and practice appears suboptimal with 70% of American melanoma patients indicating that they have never been advised to do it.[12] We have found similar evidence of under preparation to conduct and performance of TSSEs in a UK population.[13]

Evidence from randomised trials suggests that people can be appropriately trained to conduct TSSEs.[14,15,16,17,18] However it is less clear whether TSSEs, once learned, can be sustained. Recent qualitative evidence suggests that the intention to conduct TSSEs wanes with time.[13] Digital technologies are becoming more prevalent in society, with a recent report that 49% of UK homes own at least one smartphone, tablet and computer.[19] More and more people are using personal electronic devices such as tablets and smartphones to obtain health information and to interact with healthcare providers.[20] This paper reports the development, pilot testing and preliminary evaluation of the Achieving Self-directed Integrated Cancer Aftercare (ASICA) intervention, a tablet computer based application designed to prompt and support total skin self-examination at home by people treated for cutaneous melanoma.

DEVELOPING THE ASICA INTERVENTION

Overview

Our approach was based on the key development activities outlined in the MRC Framework for the development and evaluation of complex healthcare interventions.[21,22] Our approach comprised a number of activities which:

A) **Generated evidence** on how technology has been used in cancer follow-up, how people with melanoma perceived this technology that could be used to support them to conduct TSSEs, and how to target technology at those patients with most potential to benefit.

B) **Identified and developed theory** grounded in Information Motivation Behaviour Skills (IMB) as an explanatory model combined with Control Theory and Implementation Intentions to underpin the theoretical development of the intervention.[23,24,25,26,27]. The IMB model proposes three requisites for engaging in preventive behaviours: individuals must have access to relevant information; be motivated to act; and be both capable and confident (self-efficacious) enough to carry out the behaviour in question . IMB has been used successfully to explain and change health relevant, preventive behaviours; for example an IMB based intervention was more effective than information alone in increasing HIV prevention behaviour (condom use) in truck drivers. [23,28]Control theory, first proposed in 1982, proposes that behaviour is maintained through monitoring and evaluation of the discrepancy between goals and current behaviour via a discrepancy-reducing feedback loop.[25,29,30] A specific goal (e.g. performing TSSE) is compared with current behaviour and if a discrepancy is detected, action is taken to bring behaviour closer into line with the goal. If the behaviour gets closer to the goal in response to feedback, the behaviour persists but if the discrepancy is perceived to be too great the individual may disengage from the behaviour. Interventions based on Control Theory

are consistently shown to be effective in changing health related behaviours in clinical and non-clinical populations.[31] For example, in a meta-regression examining interventions to change health-related behaviours in 122 studies, the most effective interventions included techniques based on Control Theory (self-monitoring goal setting, specify action goals, feedback and review of goals).[32] A third model used in the current study concerns 'implementation intentions' or 'action plans'.[26,27] Action Plans are short 'if-then' plans that have been shown to be effective in enabling individuals to achieve their behavioural goals in a wide range of contexts. Thus IMB theory proposes the factors needed to engage in a target behaviour - information, motivation and skills/confidence, and Control Theory and Action Plans indicate the processes necessary to keep the behaviour going (goal prioritisation, feedback, behavioural discrepancy detection), and the techniques that can be used to help individuals achieve and maintain target behaviours. Using these models the components for a potential intervention were theorized in consultation with experts in behavioural science, and the mechanism for the whole intervention to prompt, record and respond to TSSEs by patients in their own homes was conceptualized and implemented using Behaviour Change Techniques (BCTs).

C) **Modelled the process** of delivery of the combined components of the intervention. A major challenge to this project was to combine the theory and evidence-based components into a viable intervention and we used innovative methods to simulate the full intervention. This was done using an experience laboratory event facilitated by experts where healthy volunteers simulated the processes of the theorized ASICA intervention.

D) **Assessed the feasibility and acceptability** of the prototype ASICA intervention (figure 1) through a pilot exercise with a group of patients supported by a nurse specialist in dermatology.

A) Generating the evidence to use and target technology

Evidence was derived from three sources. First, a systematic review was conducted to determine how technology has been used to support people with cancer. The methodology and results of this systematic review are reported in detail elsewhere.[33] Second, interviews were conducted with 21 people previously treated for cutaneous melanoma. Full ethical approval for the interviews was sought from the North of Scotland Research Ethics Committee and granted on 2nd May 2012. The methodology and results of these interviews are reported in detail in a previous publication.[13] Third, clinical data were sought and obtained where available on recent recurrences and new primary melanomas diagnosed in Northeast of Scotland. The methods to obtain, analyse and interpret these data have been reported in detail.[6]

When integrated, this evidence suggests that the technology to deliver cancer follow up care remotely is available, safe and acceptable. Furthermore, people treated for cutaneous melanoma can see the benefit of conducting TSSEs but feel ill-equipped to perform it properly, safely, regularly and sustainedly. They can, however, see the potential of technology to support them in this endeavour and want to be shown how to conduct sequential TSSEs and then reminded when and how to do it. They also believe that this process could be supported by repeated reference to an instructional resource (e.g. a video) and self-reference (e.g. a digital skin map). Once they have conducted a TSSE they want to be able to report their findings quickly to a specialist and be reassured that the specialist would check their report and respond quickly if there were concerns. They would also welcome the potential opportunity to engage with healthcare professionals from their own homes without inconvenience (travel, time off work, parking). This was especially so for rural dwellers.

The evidence garnered from the literature and interviews also found that potential recipients strongly felt that approaches to monitor potential recurrence need to be developed carefully, and should not replace current hospital based follow-up until their safety and efficacy have been proven. The clinical data also suggested that recurrence is relatively common, occurs early and is usually found at the follow-up clinic within the first year. Therefore, an intervention to support TSSEs should be implemented within a month or so of diagnosis to afford maximum benefit.

B) Identifying and developing theory

The research team included an academic GP, a health services researcher, two health psychologists, and two computer scientists). Together, they had expertise in intervention development and evaluation, behaviour change and translating behavioural interventions into programmed computer applications. The chief investigator (an academic GP) first conceptualized the aims, processes and outcomes that the digital intervention should achieve. The final theoretical intervention was then produced in a series of three consensus meetings involving the whole research team.

The overriding aim of the intervention was to prompt the performance and reporting of good quality TSSEs by people previously treated for cutaneous melanoma. To achieve this, individuals must be shown how to use technology to conduct optimal TSSEs and then be prompted to conduct TSSEs regularly. They need to be able to remind themselves how to undertake TSSEs when they are due to do it. The intervention must then transmit the result of each patient's TSSEs to an overseeing clinician who will then respond appropriately (i.e. employ clinical triage) when a patient did identify a concern.

These aims, processes and outcomes were agreed at the first consensus meeting of the whole research team. Consideration was then given to the most appropriate theoretical model able to inform an intervention to achieve these aims, support the necessary processes and deliver the desired outcomes.

By consensus with the research team, it was decided that the Information-Motivation-Behaviour model offered the most promise in explaining current use of TSSEs.[23] Using this model the components for a potential intervention were theorized (i.e. components that would provide information about TSSEs, motivate individuals to perform TSSE and develop skills and confidence to perform TSSE) and the mechanism to prompt, record and respond to TSSEs by patients in their own homes was conceptualized. This is illustrated in figures 2a and b.[23,24]

At a second consensus meeting the results of the interviews conducted at stage A were considered. It was felt that, while the explanatory outline was based on the IMB, the results of interviews A indicated that, while patients required more information, they were already highly motivated and we therefore required a theory that guided the translation of motivation into action. The psychologists proposed that the process of the intervention should therefore incorporate Action Planning and should be revised to be additionally guided by 'Control Theory' as this theory deals with the process of self-regulation to change behaviour from a pattern that fails to achieve the person's goal to one that achieves their goal.[23,24,25] Together, these theories outline the process of change and give some guidance on the behaviour change techniques (BCTs) (i.e. the active ingredients that make up an intervention and are required to change behaviour) which the intervention required.[34] Some techniques were required to develop the knowledge and behavioural skills to enact the behaviour (e.g. demonstrating the behaviour, rehearsing/practising TSSEs), some to enhance/maintain the

person's motivation to engage in the process of TSSEs (e.g. providing information on health consequences of the behaviour (TSSEs), using a credible source for the information), some to enhance confidence that they could conduct TSSEs successfully (e.g. mastering the skills necessary), and some to enable self-regulation of action, especially remembering when to act (e.g. prompts and cues) and the sequence of actions necessary for the optimal clinical outcome (e.g. Action Planning, where patients who have decided to do TSSEs would make a clear plan when, where, and how they would do the examination). Planning 'how' to perform TSSE might include involving someone else (e.g. to examine areas of skin that they cannot easily see themselves), and planning 'when' to receive a reminder. In addition, some techniques were designed to maintain continued engagement in the behaviour (e.g. receiving feedback)[26,27].

To produce the final theoretical intervention a final consensus meeting was held. The whole research team first discussed the fidelity of the theory to the delivery of the intervention, and then worked together to map a theoretical structure for the intervention, incorporating the identified BCTs where appropriate. The intervention demonstrated the target behaviour (with a video clip); enhanced motivation to perform TSSE (with recorded information about the consequences of performing/not performing TSSE); enhanced confidence (with the incorporation of step by step instructions and opportunities to try each step into the video clip). The intervention tackled the issue of intentional and non-intentional non-adherence (including forgetting, deferring, avoidance or deciding it is unnecessary) (using cues to prompt individuals to undertake TSSEs); provided individuals with feedback about the behaviour (by sending TSSE results to health professionals and having the professional reply); and checked adherence to TSSE (by asking individuals to mark skin maps/record how long the personal skin check took). This gave an indication of thoroughness and provides information on those who do it more quickly because, for example, they have other

commitments, or those who choose to adopt avoidance. This allows the monitoring of adherence and engagement. A strategy to identify avoidance is very important since, without it, clinicians could be making clinical decisions and providing clinical advice based on incorrect information.

C) Modelling the process of delivery of the intervention

Experience Laboratory Event

An Experience Laboratory event was held in May 2013 at Glasgow School of Art's Centre for Design Innovation, in Forres, Moray.[35] This facility enables the creation of different environments to simulate real-life situations. The processes of delivery for the ASICA intervention, including simulation of the clinical sequences, were developed for use at the event. This included a simulation of the information and TSSEs demonstration for a potential supporting digital application, which was produced and embedded upon a hand-held tablet computer, with guidance from experts in design and presentation. Three locations were constructed: a patient bedroom **[Photo 1]**, a GPs surgery, and a clinical nurse specialist's office, the latter two being equipped with video-conferencing capability. The intervention components included in the simulation were: the cue to action (i.e. the prompt to complete TSSEs); the instructional video (showing how to conduct TSSEs); the skin-map (to be used while conducting TSSEs) and the report sent to health professionals (following completion of TSSEs).

The Experience Laboratory event was facilitated by design experts and attended by five patient volunteers (one supported by a helper) unaffected by cutaneous melanoma who performed a simulation of the theoretical intervention (as shown in figure 2b), a GP, a clinical nurse specialist in dermatology and the researchers.

Following an initial briefing session an existing instructional video produced by MASCOT (Melanoma Action and Support Scotland) describing how to conduct TSSEs was viewed by all participants. Two scenarios were constructed and enacted by each of the patient volunteers. In the first, the volunteers were asked to perform TSSEs at which no problems were detected. In the second scenario, the volunteers conducted TSSEs at which a new mole was detected. In this latter scenario the patient attended the GP surgery location for a video consultation between themselves and the co-located GP, and the remote clinical nurse specialist.

A professional TV company filmed and edited a video of the proceedings. At the conclusion of the day all participants viewed the video and a feedback and a debriefing session was held.

Integrating components and processes of the ASICA intervention

The Experience Laboratory enabled participating stakeholders to articulate and agree the benefits which the ASICA intervention could deliver to recipients. Furthermore, the activity enabled the theoretical components of the intervention to be operationalized in the simulation in order to gain insight into how well they integrated and served the purposes for which they were intended i.e. to support the mechanism of prompting, recording and enabling a response to TSSEs. The Experience Laboratory also enabled the researchers to gain insight into the detailed processes and the sequence in which they should occur to support the effective operation of the ASICA intervention. These were: the language used; training of the user; reporting to the specialist, and receiving feedback from the specialist. The detailed learning achieved on each component is also summarised in appendix 1.

Combining processes and components in a prototype intervention

As a result of the Experience Laboratory event, the detailed components and processes identified and developed during the theoretical stage were integrated into a prototype ASICA intervention, including a supporting digital application which was designed to run on a Google Nexus 7 tablet computer. Distinct from the application were several other components including:

1. The structured training session required at inception.

2. The initial and recurring cue to action required to remind the patient to conduct a personal skin check. The need for this to be a separate trigger (sent by email or text message to the recipient's mobile phone) was necessary to avoid the risk that the tablet was used only for skin checks with the risk that the prompt would not be received.

3. The specialist response, a telephone call from the overseeing specialist nurse within 24 hours, since both the human contact and immediacy were perceived as important reassuring factors when a patient could be anxious.

Based on the Experience Laboratory findings, the prototype intervention was adjusted for piloting. The need for clear and simple language unifying the application and supporting processes was perceived to be key to user engagement and intervention adherence. Within the digital application, language was made consistent with the language introduced at the training session. This was carried over into an animated instructional video which was produced and divided into chapters based upon body areas and used as a means to demonstrate and remind users about the specific behaviours required to check their body. Conducting the personal skin check using the application was designed to follow a logical sequence supported by a check-list for self-monitoring of completion. The process of feeling for lumps in regional nodal areas was routed so that only the appropriate nodal area was examined by each patient. Patients are also able to check an integrated individualized skin-map (formed of a series of

professionally produced clinical photographs of each patient) to determine whether skin lesions were new or changing. This function was further supported by the application storing previous reports/images for future reference. At the conclusion of the skin-check the ASICA application delivers a message that either no problem has been reported, or in the event that a symptom concern has been raised, that a specialist will be in touch within 48 hours with further advice. In either eventuality, the completion of the TSSEs is recorded and acknowledged giving a sense of completing the processes in a way that provides feedback and reassurance; this acts as a reward for completing the behaviour with the aim of reinforcing the behaviour so that individual patients will keep using the ASICA application.

D) Pilot study of the feasibility and acceptability of the prototype ASICA Intervention

The prototype ASICA intervention, including the supporting digital application, was subject to a pilot study of feasibility and acceptability amongst 20 people who had previously been treated for cutaneous melanoma. Full ethical approval for the pilot study was sought from the North of Scotland Research Ethics Committee and granted on 10th June 2013

Recruitment

Six practices were purposively selected to represent geographical spread within the NHS Grampian region of Scotland, and a GP from each was invited to a training meeting to have the protocol explained. The lead GP at each practice identified and approached potential participants for pilot study. Eligible patients were aged over 18, had been diagnosed and treated for cutaneous melanoma within the preceding five years, were currently receiving hospital-based follow-up, and had no nodal involvement or metastases (i.e. in-situ to stage 2C). The 20 people agreeing to participate were identified to, and approached by, the research team. The characteristics of participants are shown in table 1. Recruits attended the Medical Illustration department at the University of Aberdeen to have a full personal body mapping

digital photography taken. These were subsequently hosted on a secure server and could be accessed by individual patients to refer to during subsequent skin checks.

Participant Training

Three training sessions (each of two hours duration) were held in Aberdeen. The meetings followed a structured programme. Participants were introduced to the study and its purposes. The fact that the intervention was experimental (and additional) to their ongoing follow-up was stressed to ensure default from follow-up was not suggested. Participants were instructed in the use of the application and tablet, including how to access their digital skin maps, and their understanding and ability to comply checked. Patients were given detailed instruction manuals for both the tablet and the application. The project researcher arranged an individual meeting with one individual that was not able to attend the training sessions. To prepare for a future clinical trial a questionnaire was modified, with permission, from one used previously.[15,16,17] The questionnaire (included as appendix 2) sought information about respondents' skin cancer history, their skin self-examination practices and intentions, their attitudes, beliefs, self-efficacy and intentions about conducting skin self-examination, the Hospital Anxiety and Depression scale, information about comorbidities and their demographic characteristics. Participants were asked to complete the questionnaire upon arrival at their initial training session. They were then sent the questionnaire again at the conclusion of the pilot.

Process

Participants were sent a monthly email reminding them that it was time to conduct their personal skin check. Upon receipt of the reminder it was intended that they would use the ASICA application to help them systematically examine their skin and through the application they were able to view the integrated instructional video chapters to enable them

to do this. A structured electronic report pro-forma was available for completion. Where a new lesion was identified either at the previous melanoma site or a new one, participants were able to complete a free-text description and/or attach a photograph taken using the tablet's camera function. Completed reports were then sent electronically to a secure and remote server. The returned reports were communicated to, and reviewed by, an overseeing nurse specialist. Figure 1 illustrates the TSSEs procedure supported by the ASICA application. Where patients had identified concerns they were contacted by telephone within 24 hours by the reviewing nurse specialist who either provided reassurance or invited them to an upcoming clinic for subsequent review. At the conclusion of the pilot study all continuing participants were invited to attend for a total skin examination at their GP surgery and 15 accepted this invitation and attended. Three declined, one because he has regular private skin checks, one because he was on holiday at the time of the appointment, one because he was undergoing treatment for metastatic melanoma, and one did not attend.

At the conclusion of the pilot the project researcher SH contacted all participating patients and the overseeing clinical nurse specialist to conduct a brief telephone interview. These interviews aimed to capture the practical experiences and personal reflection of participants in the pilot study. They were conducted to identify participants' perceptions of strengths and weaknesses with the components, or the process and delivery of the intervention, so that subsequent improvements could be made. The interviews were guided by a topic schedule. Questions focused on patients' perceptions of the strengths and weakness of the ASICA application and how it had functioned. The interviewer also gathered information about how well the technical aspects of the intervention had worked from the nurse-specialist and patient perspective. The interviews were conducted by telephone and were recorded and transcribed for subsequent analysis and reflection by the research team.

As this was a pilot study no *apriori* hypotheses were determined based on clinical or psychological outcomes. We did, however, ask participants to complete a questionnaire seeking information about clinical, behavioural and psychological outcomes to aid preparation for a subsequent clinical trial.

Pilot Study Results

a) Feasibility

Details of the number and regularity of the skin checks participants performed during the pilot can be seen in table 2. Of the 20 participants, 15 complied well and eight reported no symptoms during the six-month pilot, seven reported at least one issue to the overseeing clinical nurse specialist. Most issues were resolved by submitting further images under the direction of the specialist nurse, with a corresponding telephone call. Two participants subsequently had the lesions spotted during personal skin checks removed, one was a recurrent melanoma and the other was a benign lesion. Of the three less compliant participants one regularly checked only his face where his original primary had been, another checked selected areas less regularly, citing work pressures and lack of time to conduct TSSEs. Another, a busy mum who stated she found it difficult to make time to conduct a TSSEs, checked their skin only once, on that occasion reporting three issues of concern to the overseeing nurse specialist. One participant withdrew for undisclosed personal reasons.

With respect to the technical operation of ASICA the nurse specialist stated that on the few occasions when photographs of new skin lesions had been submitted by participants these were typically of insufficient quality on which to base clinical judgements. However, in almost all cases he was able to contact the patient and direct them to take improved images. As a result guidelines to take good quality images have been incorporated into the revised app.

b) Acceptability

Patients were largely positive about their experience of using ASICA. The user-friendliness of ASICA was highlighted, along with views that participation supported good habits, allowed participants to become familiar with their own bodies, and provided them with empowerment and reassurance. Table 3 describes comments which reflect these themes. Technical issues raised by patients fell into three categories. There were minor issues with the interface (e.g parts of electronic buttons being obscured) which have been modified. Some patients, especially those in the more remote rural areas, were troubled by issues related to their internet connection. These are less easy to resolve but are likely to be more common in this particular geographical location than in the majority of the rest of the UK. Government initiatives and technological advances will help going forward in this regard. Similarly, there were some issues with the hardware, for example a malfunctioning charger in one case and a damaged screen in another.

c) Piloting trial procedures

Sixteen participants completed and returned the questionnaire at baseline and outcome. The data are not presented in detail. There were non-significant increases in the proportion of respondents indicating that they intended to check their skin at least monthly, and in the proportion indicating that they would be confident to perform total skin self-examination. No significant changes were observed between baseline and outcome in anxiety, depression or cancer worry. These data will however, be informative in determining power for a subsequent randomised trial.

DISCUSSION

Principal findings

The authors have developed a feasible clinical intervention process based on a digital tablet-based application to prompt, record, and respond to regular total skin self-examination by people previously treated for cutaneous melanoma. This has proven to be acceptable and safe for patients to use. There is also preliminary evidence that it can help reinforce and sustain TSSEs in a way that has not previously been possible. Further, there is some early evidence that it can bring new skin problems to medical attention sooner than would otherwise have been the case. It must also be noted however that the fact that a minority of patients did not comply, or complied only partially, indicates that ASICA will not compel all patients to conduct regular TSSEs or might require tailoring for some patients.

Strengths and limitations

Strengths

The approach adopted for developing the ASICA intervention had several inherent strengths. Developing interventions that employ digital technologies to deliver aspects of healthcare in a completely new way is immensely challenging. For this reason our approach benefited from employing the structured, iterative and well-rehearsed approach advocated by the MRC framework.[21,22] The use of the Experience Laboratory allowed simulation of the complete intervention, integrating components based on theory and evidence. The experience of the team in following this approach and the strong theoretical underpinning of the IMB and Control Theory models allowed the project to be phased and focused.[23,24] We involved key stakeholders – potential patients, clinicians, technology specialists, behaviour change intervention specialists, health service researchers – at each stage of the process so that their perspectives were identified and incorporated throughout. Furthermore, adopting this multidisciplinary approach enabled an ongoing understanding of the full spectrum of

potential challenges and caveats which the intervention was required to overcome, complemented by an ability to exploit the enablers perceived by each group. We were also able to ensure that we optimised the potential of the ASICA digital application, identifying the necessary processes and components, and ensuring that they were developed and embedded within the intervention in the most effective way.

Limitations

Some limitations must be acknowledged. The pilot was conducted on a small scale within Northeast Scotland. Clearly, this has implications about the representativeness of our participants. In terms of the whole Scottish population they were relatively affluent and also willing to learn about technology. It was assumed that all patients were physically capable of using the tablet and the application, but one could not use their fingers and required to be supplied with a stylus. There were other disabilities that were not provided for, for example poor eye-sight, lack of proficiency in English and restricted physical movement. A range of adherence was observed during the study and we were unable to understand this in detail. ASICA, as currently configured, will not suit everyone, but it may be possible to tailor it to individual need. While the developed intervention may have greater value and relevance among people familiar with technological advances and in localities where the clinical service is delivered to patients living remotely from the clinical centre, it is likely to have utility among a broad range of patients after melanoma diagnosis and treatment. This view is supported by noting that people with melanoma from stage 0-2C were willing to take part.

These limitations must be viewed against the backdrop of societal trends to embrace modern technology, and an increasing appetite amongst clinicians and policy makers to diagnose and manage skin cancer using digital means. A recent review, for example identified 40

applications of divergent quality and developmental rigour, for monitoring and diagnosis of pigmented skin lesions.[36]

Context with other studies

Where interventions have been specifically developed to improve TSSEs practice, and subjected to randomised trial the results have been disappointing, although the recruited patient groups have been different to this pilot study. Two randomised trials, one in a general US primary care population and another in Australian men over 50 at increased risk but with no previous melanoma, educated using brochure or video demonstrations only, reported increased TSSEs practice for 3-7 months, with participation returning to baseline after one-year.[14,15,16,17] A further study, employing a nurse or physician delivered an educational module supported by a personal skin map to US patients but referred to a secondary care pigmented lesion clinic, reported significant increases in TSSEs practice at 4 months.[18] Previous trials are informative to the current intervention for three reasons. First, all three were conducted in patients at increased risk, rather than patients actually treated for melanoma. It is therefore likely, that the target group of the ASICA intervention will be more motivated to conduct and sustain TSSEs than previously studied groups. Second, previous intervention development provides evidence that several of the components developed using health psychology-based approaches and incorporated into ASICA (such as the instructional videos, personal skin maps, cues to action and sample photographs) have the potential to promote and sustain, at least in the short-term, TSSEs in patients who form a lower risk group than the ASICA target population.[14,15,16,17,18] Third, and perhaps most importantly, the interventions previously trialled have comprised one-off educational activities with the issue of videos, booklets or brochures to patients for subsequent personal use.[14,15,16,17,18] ASICA, on the other hand, will use familiar everyday technology to prompt and sustain the

behaviour over time, in participant's own homes which should increase the likelihood of success.[37]

Lessons learned from this study

Evidence for components of previous interventions that have sustained TSSEs in the medium term has been translated onto a theoretical intervention based on well-evidenced theoretical models using the Behaviour Change Techniques Taxonomy v1 to implement the active behaviour change mechanisms.[34] We have learned that a skilfully facilitated experience laboratory can be used to provide rapid feedback on a theoretical and simulated intervention prior to its initial development and testing in a full-scale pilot trial. Finally, we have used carefully assembled theory and knowledge to build a working proto-type of an actual digital intervention to support TSSEs by people previously treated for cutaneous melanoma. This has functioned well in a real world pilot. It has succeeded in actually supporting, and responding to TSSEs, in a group of patients, who have appreciated and enjoyed using it. We have learned that it is a feasible and desirable intervention. We have also learned about the minor modifications that are required to proceed to a definitive clinical trial employing the ASICA intervention. Such a trial, conducted at several UK centres to ensure wider applicability, should now follow shortly, so that we can consolidate the promising findings reported here with definitive evidence of ASICA's role in future melanoma follow-up.

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CONTRIBUTORS

PM conceived the original intervention. SH conducted the initial exploratory interviews. The theoretical intervention was mapped by PM, SH, MJ, JA and translated into a working prototype by JM and MD, with advice on national implementation potential from FW. JM and MD developed the patient training sessions and materials, and the training was delivered by PM, JM, MD and SH. BB delivered the intervention. PM, SH, MD and FW generated and analysed the data. PM wrote the manuscript with contributions from all authors.

COMPETING INTERESTS

All authors have completed the Unified Competing Interest form at www.icmje.org/co_disclosure.pdf (available on request from the corresponding author) and declare that (1) None of the authors have support from any commercial company for the submitted work; (2) PM, JA, BB, MD, SH, JM, FW and MJ have no relationships with any commercial company that might have an interest in the submitted work in the previous 3 years (3) their spouses, partners or children have no financial relationships that may be relevant to the submitted work; and (4)) PM, JA, BB, MD, SH, JM, FW and MJ have no non-financial interests that may be relevant to the submitted work.

ETHICS APPROVAL

Full ethical approval for the interviews with people previously treated for melanoma study was granted by the North of Scotland Research Ethics Committee on 2nd May 2012. (REC reference number: 12/NS/0039). Full ethical approval for the pilot study was granted by the North of Scotland Research Ethics Committee on 10th June 2013. (REC reference number: 13/NS/0062)

STUDY SPONSOR

The University of Aberdeen is the study sponsor. PM, JA, MD, SH, JM and MJ are employees of the University of Aberdeen but all researchers were independent from the sponsor and funders in study design, the collection, analysis and interpretation of data, the writing of the article and the decision to submit for publication.

DATA SHARING STATEMENT

Process data about how ASICA performed during the pilot exercise and which does not identify patients, along with the technical specifications of the ASICA digital application may be available upon application to the corresponding author.

FIGURE LEGENDS

Figure 1: TSSEs Procedure as Supported by the ASICA application

Figure 2a: Model demonstrating theoretical processes of ASICA according to Information-Motivation-Behaviour Skills (IMB) model – adapted from Cowling et al, 2011

Figure 2b: Schematic demonstrating operationalization of components and processes of ASICA intervention adapted from Cowling et al, 2011.

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Table 1: Characteristics of pilot study participants

ID	Age	Gender	Place of Residence*	Date of Mel Dx	Site	Stage
001	46	F	Accessible rural	2010	Arm	1.1mm Stage 1B
002	49	F	Other urban area	2012	Knee	0.5mm Stage 1A
003	72	F	Accessible rural	2013	Arm	0.4mm Stage 1A
004	69	M	Urban	2013	Breast	0.8mm Stage 1A
005	62	M	Remote rural	2012	Eyelid	M in situ Stage 0
006	66	F	Remote rural	2011	Cheek	0.3mm Stage 1A
007	72	M	Remote small town	2009	Cheek	2.8mm Stage 2A
008	70	M	Remote small town	2012	Shoulder	0.3mm Stage 1A
009*	41	F	Remote rural	2011	Back	>1mm
010	67	F	Accessible rural	2009	Arm	3mm Stage 2A
011	78	M	Remote small town	2008	Eyebrow	2.6mm Stage 2A
012	42	F	Accessible small town	2011	Back	M in situ Stage 0
013	75	F	Accessible rural	2009	Thigh	1.1mm Stage 2B
014	67	M	Accesible rural	2013	Shoulder	2mm Stage 2A
015	46	F	Accesible rural	2011	Abdomen	0.6mm Stage 1A
016	72	M	Accessible rural	2011	Forearm	1mm Stage 1B
017	65	M	Accessible rural	2014	Shoulder	M in situ Stage 0
018	69	M	Remote rural	2009	Shoulder	1.5mm Stage 1B
019	44	M	Accessible rural	2012	Abdomen	1.5mm Stage 1B
020	44	F	Accessible small town	2010	Lower leg	0.42mm Stage1A

Classifications from Scottish Government Urban-Rural Classification[38]

*Staging data were not available for this patient

Table 2: Compliance with intervention and outcome of monthly skin checks

Patient	Month 1 (May)		Month 2 (June)		Month 3 (July)		Month 4 (August)		Month 5 (September)		Month 6 (October)	
	Number of body areas checked	Changes reported	Number of body areas checked	Changes reported	Number of body areas checked	Changes reported	Number of body areas checked	Changes reported	Number of body areas checked s	Changes reported	Number of body areas checked	Changes reported
N=8: Complied well, reported no symptoms												
P02	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**
P03	**0**	**0**	**0**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**0**	**0**
P04	**5**	**0**	**5**	**0**	**5**	**0**	**0**	**0**	**0**	**0**	**5**	**0**
P05	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**
P06	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**
P10	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**
P16	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**
P19	**5**	**0**	**0**	**0**	**5**	**0**	**0**	**0**	**5**	**0**	**5**	**0**
N=7: Complied well, reported symptoms												
P01	**4**	**1**	**0**	**0**	**5**	**2**	**5**	**2**	**4**	**1**	**5**	**0**
P07	**5**	**3**	**5**	**5**	**5**	**2**	**5**	**0**	**5**	**2**	**5**	**0**
P08*	**4**	**0**	**5**	**0**	**5**	**0**	**5**	**2**	**5**	**0**	**5**	**1**
P13	**3**	**3**	**1**	**1**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**
P14	**0**	**0**	**3**	**2**	**4**	**0**	**5**	**1**	**5**	**0**	**4**	**0**
P15	**5**	**1**	**0**	**0**	**5**	**1**	**5**	**0**	**5**	**0**	**5**	**0**
P18* **	**5**	**1**	**0**	**0**	**5**	**0**	**0**	**0**	**5**	**1**	**0**	**0**
N= 3: Complied less well, reported symptoms												
P11**	**1**	**1**	**1**	**1**	**1**	**0**	**1**	**1**	**1**	**1**	**1**	**1**
P12	**0**	**0**	**1**	**0**	**0**	**0**	**3**	**1**	**0**	**0**	**0**	**0**
P17	**0**	**0**	**0**	**0**	**3**	**3**	**0**	**0**	**0**	**0**	**0**	**0**
N=1: Complied poorly, reported no issues (P20												
P20	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**5**	**0**	**0**	**0**
P09 PATIENT WITHDREW CITING PERSONAL CIRCUMSTANCES MAKING SKIN CHECKS DIFFICULT – NOT CLEAR WHAT THESE WERE												

*P8 diagnosed with recurrent melanoma after excision of lesion noticed during personal skin check

**P11 checked head and neck only

***P18 diagnosed with benign lesions on both legs after excision of lesions noticed during personal skin check

Table 3: Comments from patient interviews reflecting views on usability and acceptability

A USER FRIENDLY DEVICE P03 – "Yes, it was quite clear the actual information that we were given, very clear, beautifully set out, very easy to use and understand. P04 – "Very good. Very good indeed. It's very clear, easy to understand and useful in tips about parting your hair and getting somebody else to check the back of it for you and things like that, yeah, very clear and easy to understand and you know, tips about how to do awkward places on yourself, yes. P05 – "So what I've done is have a good look at myself over the preceding days, if you know what I mean, just as and when it was comfortable. And really handy, when I was getting changes, getting up or going to bed or what have you, in the shower. And then just rattle through the app. P08 – "The animations that were provided I thought were a really good guide, for somebody that's not used to technology it was really simple." P17 – "Well it tells you exactly what you need to know, there's no question about that." P21 – "The instructions were excellent, they were very well laid out. The videos were very helpful showing you exactly what you needed to do and how to check yourself all over."
ESTABLISHING GOOD HABITS P04 – "But the fact that it makes people do it once a month or whatever, it focuses the attention because it's something we'd probably be a bit slapdash with normally." P13 – "The tablet is great. Totally self-explanatory and the videos are very easy to watch and everything so it very easy to do and send off the report. Everything was great." P15 – "It made you really thorough about the skin check procedure. There was no way you could miss anything out. It was really good." P16 – "Yes, as I say, it's all clear and it's really good to see every part of your body…to go through it all in separate stages. Yes, it make you do it all in a through way, which is important, since I'm not getting checked at the hospital anymore, so it's really important that I've got to remember to check my whole body in case something appears."
GETTING TO KNOW MY OWN BODY P01 – "I like having the maps to look at because I've got a lot of moles but I have discovered there might be a blind spot on my arms where it's not really getting my arm – if you know what I mean? P15 – "Without this it becomes very difficult to remember if anything has changed very much since the last time you looked. This was really the first time I've ever looked really closely at my body, and I think to myself "goodness, I didn't realise I have that there before." And then I go back to the body map and – which is a salutary exercise in itself - and see "oh yes, it was there." I suppose it's getting to know your body much better." P17 – "I never used to think about it, but I know what to look for now. If I see something I know what it is, and what to do. Before, I never would have noticed." P21 – "The more I've done it over the period of months, the more that I've gotten used to where everything is on my body, where all the different moles are." P21 – "Before starting this project I probably wasn't really checking my skin that much at all, but since I've been doing this, it's been much more regular and I've been paying much more attention to it.
FEELING REASSURED AND EMPOWERED P09-"I'm very pleased with it, because it's helping me, you feel in control, that you are looking after yourself." P12 – "If somebody is checking it, that can get back to you really quickly, then off to the GP. Very re-assuring." P14 – "And because I was doing it so diligently, I felt good about that." P14 – "It a brilliant idea, especially for people who are a long way away, because you can do a really thorough check, and received professional reassurance without having to travel all the way to Aberdeen."

Figure 1: TSSEs Procedure as Supported by the ASICA application

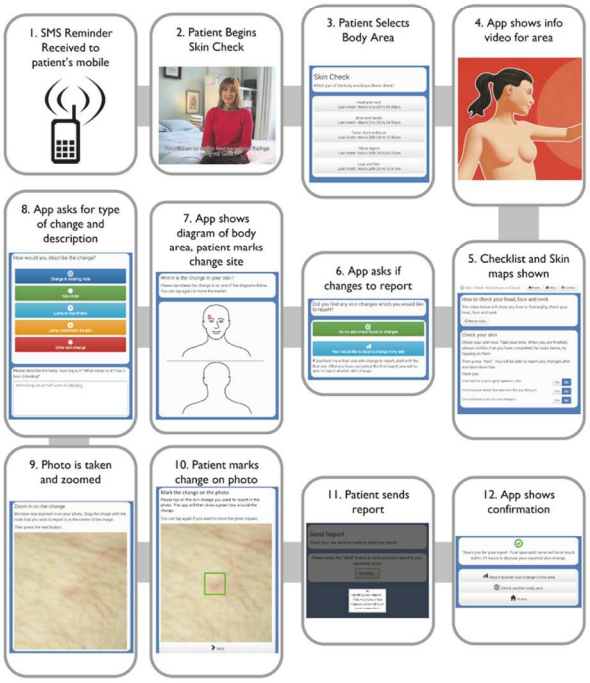

Figure 1
209x297mm (300 x 300 DPI)

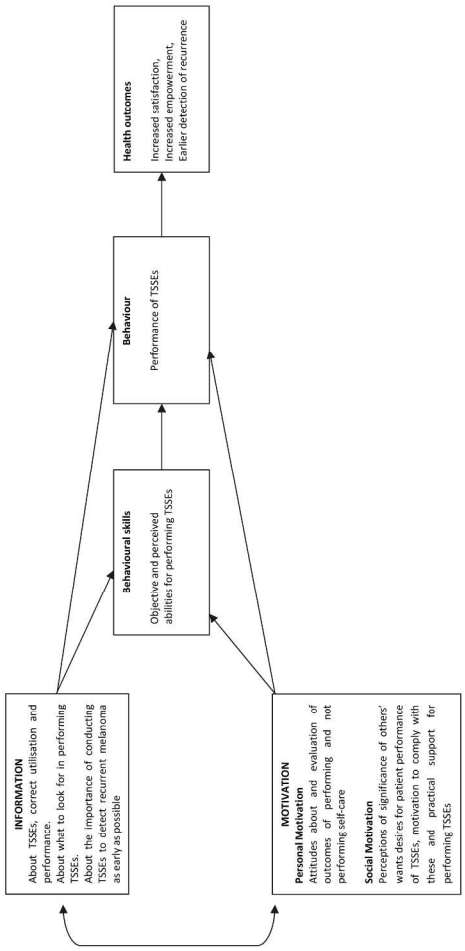

Figure 2a: Model demonstrating theoretical processes of ASICA according to Information-Motivation-Behaviour Skills (IMB) model – adapted from Cowling et al, 2011.

Figure 2a
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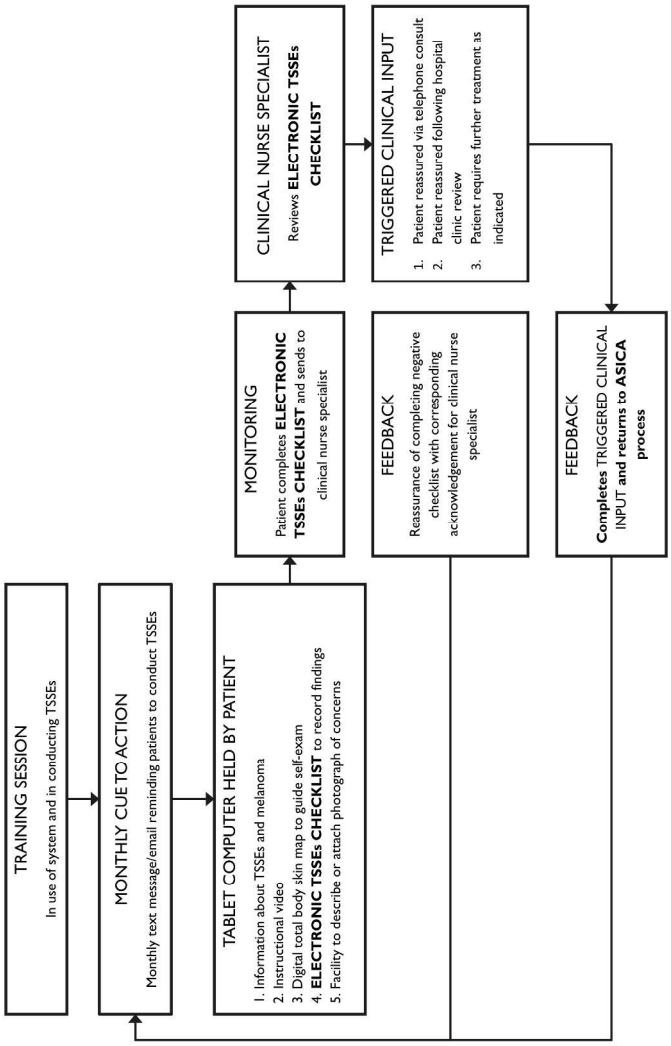

Figure 2b: Schematic demonstrating operationalization of components and processes of ASICA intervention adapted from Cowling et al, 2011.

Figure 2b
209x297mm (300 x 300 DPI)

Digitally supported total skin self-examination at home for people treated for cutaneous melanoma: developing and simulating experience of the ASICA intervention. Murchie et al

Appendix 1

This appendix displays the outcome questionnaire developed for use in a proposed future clinical trial of the ASICA intervention. It has been adapted, with permission from an instrument developed by Professor Monika Janda, Queensland University of Technology, Brisbane QLD, Australia. A related baseline questionnaire has also been prepared.

Janda M, Baade PD, Youl PH, Aitken JF, Whiteman DC, Gordon L, Neale RE. The skin awareness study: promoting thorough skin self-examination for skin cancer among men 50 years or older. Contemp Clin Trials 2009,31:119–130

Janda M, Neale RE, Youl P, Whiteman DC, Gordon L, Baade PD: Impact of video-based intervention to improve the prevalence of skin self-examinations in men 50 years or older: the randomized skin awareness trial. Arch Dermatol 2011, 147:799–806.

Janda M, Youl P, Neale R, Aitken J, Whiteman D, Gordon L, Baade P. Clinical Skin Examination Outcomes After a Video-Based Behavioral Intervention: Analysis From a Randomized Clinical Trial JAMA Dermatol. 2014;150(4):372-379. doi:10.1001/jamadermatol.2013.9313.

UNIVERSITY OF ABERDEEN

ASICA Questionnaire (Outcome)

Achieving Self-directed Integrated Cancer Aftercare

All the information that you provide in this questionnaire is confidential. You cannot be identified from any of the answers that you give.

If you have any questions regarding this questionnaire please contact:

For official use only

dot.rural
Transformation through Digital Innovation

Date returned	
Date entered	
Date checked	

What is the purpose of this

questionnaire?

The purpose of this questionnaire is to find out some things about you, your melanoma and your general health.

What if I am not sure how to answer some questions?

Do the best that you can.

Should you have any difficulties with completing the questionnaire, or have any questions about the study please contact:

How long will it take to complete?

It should take no longer than 20 minutes to complete.

Is the information confidential?

All the information that you give is extremely valuable to the study and is treated in the strictest confidence.

What should I do with my completed questionnaire?

After you have filled in the questionnaire please put it in the addressed FREEPOST envelope provided and post it back to us. NO POSTAGE STAMP IS REQUIRED

We would be very grateful if you could return your completed questionnaire as soon as possible.

Thank you

Skin Cancer History

1. Have you ever had a skin cancer, mole, or other spot/s removed or treated?

☐ 1 Yes

☐ 2 No → Go to Q4

☐ 3 Unsure/Don't Know → Go to Q4

2. How many skin cancers, moles, or other spots have you had treated?

☐ 1 One

☐ 2 Two to five

☐ 3 Six to ten

☐ 4 Eleven to twenty

☐ 5 Twenty-One to fifty

☐ 6 More than fifty

3. How old were you when you had your first skin cancer, mole, or other spot treated?

☐ Do not remember

☐ Years old

4. Are you currently concerned about a spot or mole?

☐ 1 Yes ☐ 2 No ☐ 3 Not sure

5. How likely is it, do you think, that you will get skin cancer again at some time in the future?

☐ 1 Not at all likely

☐ 2 Somewhat likely

☐ 3 Very likely

☐ 4 Don't know/not sure

Skin Self Examination

6. **Have you or someone who is not a doctor or nurse, such as your spouse or partner, ever deliberately checked any part of your skin for early signs of skin cancer.**

☐ 1 Yes ☐ 2 No → Go to Q13

☐ 3 Don't know → Go to Q13

7. **In the past 12 months, have you or someone who is not a doctor or nurse , such as your spouse or partner, deliberately checked any part of your skin for early signs of skin cancer.**

☐ 1 Yes ☐ 2 No → Go to Q13

☐ 3 Don't know

8. **In the past 12 months, how often have you or someone who is not a doctor or nurse checked any part of your skin for early signs of skin cancer?**

☐ 1 One to two times ☐ 3 Five to six times

☐ 2 Three to four times ☐ 4 More than six times

9. **In the past 6 months, how often have you or someone who is not a doctor or nurse checked any part of your skin for early signs of skin cancer?**

☐ 1 One to two times ☐ 3 Five to six times

☐ 2 Three to four times ☐ 4 More than six times

☐ 5 Zero

10. **Thinking back to the last time you or someone who is not a doctor or nurse checked your own skin, which areas of your body did you actually check?**

☐ 1 Face ☐ 8 Feet

☐ 2 Neck ☐ 9 Back of thighs/knees/shins

☐ 3 Upper Chest ☐ 10 Bottom

☐ 4 Arms ☐ 11 Lower Back

☐ 5 Hands ☐ 12 Higher Back

☐ 6 Torso ☐ 13 Back of Neck/Scalp

☐ 7 Front of thighs/knees/shins ☐ 14 Whole Body

11. During your last check, did you use a handheld mirror or full-size mirror to check difficult to see areas of your skin such as your back?

☐ 1 Yes, hand-held mirror ☐ 4 No

☐ 2 Yes, full-size mirror ☐ 5 Don't know

☐ 3 Yes, both

12. During your last check did you have someone to help you see difficult to see areas for example your wife, partner or another relative?

☐ 1 Yes ☐ 2 No ☐ 3 Don't know

13. In the next 12 months, how many times do you intend to check your skin for early signs of skin cancer?

☐ Please write the number in the box.

We would now like to know *how confident* you are about being able to check your skin. Please *circle the number* that best describes your level of confidence for each of the following four questions.

14. How confident are you that you can check your own skin correctly?

1	2	3	4	5	6	7	8	9	10
Not at all Confident				Moderately Confident					Highly Confident

15. How confident are you that you will find the time in the next 12 months to check your own skin.

1	2	3	4	5	6	7	8	9	10
Not at all Confident				Moderately Confident					Highly Confident

16. How confident are you that you will remember to check your own skin at least once a month.

1	2	3	4	5	6	7	8	9	10
Not at all Confident				Moderately Confident					Highly Confident

17. How confident are you that if you find a spot or mole of concern that you will take appropriate action.

1	2	3	4	5	6	7	8	9	10
Not at all Confident				Moderately Confident					Highly Confident

18. When you last checked your own skin, did you find a spot or mole of concern?

☐ 1 Yes → → Go to Q19

☐ 2 No → → Go to Q21

☐ 3 Don't know/unsure → Go to Q21

☐ 3 Did not check my skin → Go to Q21

19. If yes, what did you do?

☐ 1 Watched it for up to one month

☐ 2 Watched it for longer than one month

☐ 3 Showed it to partner/relative

☐ 4 Showed it to a doctor/nurse

☐ 5 Other, please specify ……

20. Over the next six months if you find a spot or mole that you are worried about what will you do?

You may tick one or more options

☐ 1 Show it to a partner, relative or friend

Would you do this:

☐ 1 Immediately

☐ 2 Within a few days

☐ 3 Within a week

☐ 4 Within a month

☐ 5 Other, please specify

☐ 2 Make an appointment with a doctor

Would you do this:

☐ 1 Immediately

☐ 2 Within a few days

☐ 3 Within a week

☐ 4 Within a month

☐ 5 Other, please specify

☐ 3 Contact the specialist nurse

Would you do this:

☐ 1 Immediately

☐ 2 Within a few days

☐ 3 Within a week

☐ 4 Within a month

☐ 5 Other, please specify

☐ 4 Watch it until the next prompt from the ASICA tablet arrives

☐ 5 Watch and wait

☐ 6 Other, please specify .....

Health Professional Skin Examination

21. Has a doctor or nurse ever deliberately checked any part of your skin for early signs of skin cancer since you received the ASICA electronic tablet?

☐ 1 Yes → Go to Q22

☐ 2 No → Go to Q26

☐ 3 Don't know → Go to Q26

22. In the past 12 months, has a doctor or nurse deliberately checked any part of your skin for early signs of skin cancer?

☐ 1 Yes → Go to Q23

☐ 2 No → Go to Q26

☐ 3 Don't know → Go to Q26

23. In the past 12 months has a doctor or nurse deliberately checked the skin on your whole body? Usually this would involve taking your clothes off at least down to your underwear.

☐ 1 Yes

☐ 2 No

☐ 3 Don't know

24. During your last skin check did the doctor suggest you check your own skin for early signs of skin cancer?

☐ 1 Yes ☐ 2 No

25. Did the doctor show you how to check your own skin for early signs of skin cancer?

☐ 1 Yes ☐ 2 No

Attitudes and Beliefs

For this section of the questionnaire we would like to find out what you think about checking your skin.

26. For each of the following statements please indicate whether you strongly disagree, disagree, agree, strongly agree, or are unsure with each statement. ***Please select only one option for each question.***

	Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree
a. It is important to check my skin for skin cancer even if I have no symptoms	☐1	☐2	☐3	☐4	☐5
b. Checking my skin would make me anxious.	☐1	☐2	☐3	☐4	☐5
c. Checking my skin regularly is a priority for me.	☐1	☐2	☐3	☐4	☐5
d. I could find something suspicious on my skin if it was there.	☐1	☐2	☐3	☐4	☐5
e. If I saw something suspicious on my skin, I'd go to the doctor straight away.	☐1	☐2	☐3	☐4	☐5
f. I am confident in a doctor's ability to diagnose skin cancer.	☐1	☐2	☐3	☐4	☐5
g. I have made plans about when to examine my own skin.	☐1	☐2	☐3	☐4	☐5
h. I have made plans about where I will be when I examine my skin.	☐1	☐2	☐3	☐4	☐5
i. If I don't manage to examine my skin as planned I will find another opportunity.	☐1	☐2	☐3	☐4	☐5

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How You Feel

Please read each item and place a tick in the box beside the reply which comes closest to how you have been feeling **in the past week**. Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought-out response. **Please tick only one box in each section**

1. I feel tense or 'wound up':
- Most of the time ☐
- A lot of the time ☐
- Time to time, Occasionally ☐
- Not at all ☐

2. I feel as if I am slowed down:
- Nearly all the time ☐
- Very often ☐
- Sometimes ☐
- Not at all ☐

3. I still enjoy the things I used to enjoy:
- Definitely as much ☐
- Not quite as much ☐
- Only a little ☐
- Hardly at all ☐

4. I get a sort of frightened feeling like 'butterflies' in the stomach:
- Not at all ☐
- Occasionally ☐
- Quite often ☐
- Very often ☐

5. I get a sort of frightened feeling as if something awful is about to happen:
- Very definitely and quite badly ☐
- Yes, but not too badly ☐
- A little, but it doesn't worry me ☐
- Not at all ☐

6. I have lost interest in my appearance:
- Definitely ☐
- I don't take so much care as I should ☐
- I may not take quite as much care ☐
- I take just as much care as ever ☐

7. I can laugh and see the funny side of things:
- As much as I always could ☐
- Not quite so much now ☐
- Definitely not so much now ☐
- Not at all ☐

8. I feel restless as if I have to be on the move:
- Very much indeed ☐
- Quite a lot ☐
- Not very much ☐
- Not at all ☐

9. Worrying thoughts go through my mind:
- A great deal of the time ☐
- A lot of the time ☐
- From time to time but not too often ☐
- Only occasionally ☐

10. I look forward with enjoyment to things:
- As much as ever I did ☐
- Rather less than I used to ☐
- Definitely less than I used to ☐
- Hardly at all ☐

11. I feel cheerful:
- Not at all ☐
- Not often ☐
- Sometimes ☐
- Most of the time ☐

12. I get sudden feelings of panic:
- Very often indeed ☐
- Quite often ☐
- Not very often ☐
- Not at all ☐

13. I can sit at ease and feel relaxed:
- Definitely ☐
- Usually ☐
- Not often ☐
- Not at all ☐

14. I can enjoy a good book or radio or TV programme:
- Often ☐
- Sometimes ☐
- Not often ☐
- Very seldom ☐

Other Health Conditions

This section will cover questions about diseases and health conditions that you may already have or have had in the past.

27. Has a doctor ever told you that you have or have had any of the following conditions?

PLEASE TICK ALL THAT APPLY AND GIVE YOUR AGE AT FIRST DIAGNOSIS

	No [1]	Yes [2]	Age at first diagnosis	Don't know [3]
1. Heart Conditions (Heart Attack, Coronary, Myocardial Infarction, Angina Pectoris)				
2. High Blood Pressure/Hypertension				
3. High Cholesterol/Lipid Problems				
4. Stroke				
5. Diabetes/High Blood Sugar				
6. Lung Conditions (Asthma/Chronic Bronchitis/Emphysema Chronic Obstructive Lung Disease/COPD)				
7. Stomach or Duodenal Ulcer				
8. Chronic Headaches/Migraine				
9. Musculo-skeletal Disorders (Osteoporosis, Back Problems)				
10. Arthritis (Osteoarthritis/Rheumatoid Arthritis)/other joint complaints				

	No [1]	Yes [2]	Age at first diagnosis	Don't know [3]
11. Cancer/Leukaemia (excluding skin cancer)				
12. Problems with eye sight which could make it difficult to examine my own skin				
13. Mental health problems (Anxiety, Depression, Post-traumatic Stress Disorder)				
14. Problems with mobility which could make it difficult to examine my own skin				
15. Any other prolonged or serious illness? If yes, please specify below. _____				

Please list any medication, including over the counter medicines, that you are taking in the space below.

Personal Background

And finally …… some questions about yourself.

28. Are you

☐ 1 20-30

☐ 2 31-40

☐ 3 41-50

☐ 4 51-60

☐ 5 61-70

☐ 6 71-80

☐ 7 81-90

☐ 8 91 or older

29. Do you live?

☐ On your own

☐ With a partner/spouse

☐ With other family *(Please say who)* _____

☐ Other *(Please say who)* _____

30. How would you <u>best</u> describe your current work situation?

☐ 1 Employed full-time (include self-employed/business/farming)

☐ 2 Employed part-time or casual (include self-employed/business/farming)

☐ 3 Full-time home duties/home-carer

☐ 4 Student

☐ 5 Unemployed or looking for work

☐ 6 Retired

☐ 7 Permanently ill/unable to work

☐ 8 Other (please specify) ……

31. Is your main job or activity now…?

☐ 1 Mainly indoors

☐ 2 Mainly outdoors

☐ 3 About equal amounts indoors and outdoors

32. What is your present marital status?

☐ 1 Married/living together

☐ 2 Divorced/separated

☐ 3 Widowed

☐ 4 Single/never married

☐ 5 Other (please specify) ……

33. Approximately what is the distance from your home to your GP

☐ Minutes by car

☐ Miles

34. Do you: (Please tick one box only)

☐ Own your home

☐ Rent your home

☐ Other (Please state……..)

Thank you for helping us with this important research.

If you have any comments about any of the questions that we have asked, please add them here.

Thank you for completing this survey. Please return it using the reply-paid envelope provided (NO STAMP IS NEEDED)

Digitally supported total skin self-examination at home for people treated for cutaneous melanoma: developing and simulating experience of the ASICA intervention. Murchie et al

APPENDIX 2: Experience lab outcomes

BENEFITS – "WHAT DO I GET FROM THIS?": Developing motivation to engage with ASICA and TSSE

Patient volunteers perceived the following advantages of the ASICA intervention: reduced travel and time; having your own skin map (an aide memoire and evidence if needed); speed and simplicity of the process; rapid reassurance when concerned; raised awareness of caring for my skin and empowerment; feels like the medical staff care for me; secure and I can trust the NHS with my information.

COMPONENTS – "NUTS AND BOLTS TO MAKE IT WORK": Action plans to enable TSSE and maintenance of use of ASICA

THE CUE TO ACTION

The email reminder should be sent at the right time – no point sending it on a Friday evening when the patient will be unable to get a response until the following Monday. It seems sensible, therefore, that these would be sent at the beginning of a week. It was also viewed as sensible to send this to another device/using another mechanism to get round the risk that the tablet may be stored in a drawer between skin-checks.

THE INSTRUCTIONAL VIDEO

The video to be embedded within ASICA had the following aims:

- To introduce self-monitoring
- To incentivise a personal skin check
- To provide persuasion from a credible source
- To provide behavioural instruction
- To demonstrate the required behaviour
- To provide information about health consequences

Comments on the existing video were generally negative. It was described as too long and repetitive and in need of "spicing up." However at least two of the patient volunteers warned that it needed to continue to be comprehensive.

Particular issues for improvement of the video were:

Provide incentive: There was nothing on the video that suggested participants might expect a better outcome by doing a personal skin check. This incentive does not have to be much – it could just be 'By doing this you will get early attention to any problems which the clinic can then deal with' You don't have to say you will save their lives.

Provide Information: Tell us why we are doing this and what we are looking for at each stage. Give us some information about moles (e.g. where are they most likely to be found). Tell us specifically what the things we are worried about look/feel like. Tell us how long the examination will take.

Have an inspiring voice over: The lady on the video was felt to be monotonous.

Make the background less gloomy: The dark background made the video seem oppressive.

Make the video less repetitive: Basic techniques should be explained once, i.e. examining skin and feeling for lumps.

Tailor the video: Give a video of a man for men and a woman for women.

Idealised body: Participants generally felt that a model with an "ideal" body was preferable to more realistic appearance.

Presence of moles: The model should have some moles. We should see them examining the moles as we would want them to do in the behaviour. We should also see how the patient would record this information within the intervention. This should be re-emphasis in each section of the video (i.e. after "The scalp" "The head" "The back".)

Use "point of view" perspective: To differentiate parts of the video where you are looking versus feeling. The video should make it clear that "Looking" and "Feeling" are two very different behaviours. This means that the video should emphasise both behaviours. The video should clearly distinguish between "looking" and "feeling." The video should show what people might see when they "look." Similarly, they should be shown how to "feel". This needs to be tailored to parts of the body – i.e. what are the hands doing when the patient is feeling the back of their legs. Video needs to introduce elements of how to feel for lumps, emphasising those that are practically shown at the training day.

Helpers: The EP day made it clear that people are going to be challenged to examine their back and their scalp. It might be good for the video to introduce the idea of "helpers" and a range of whom these might be – e.g. friends, spouse, carers, parents, children, GPs. It would then be good practice to ask the patients to identify an appropriate helper, a person whom they would most like to involve at recruitment. Perhaps a solution needs to be found for those that can't identify a helper.

Make the video interactive: Split into sections (e.g. head and neck, arms, legs) so that participants can tailor how they do the examination. It will also be important to structure it this way to facilitate a sequence, so that people can tick sections as they go along. The video, therefore, needs to be structured with reference to the check list which will be on the tablet. We should consider having a separate checklist for each part of the body. There is a need, however, to guard against making the system too complicated.

Consequently a new animated video was professionally produced for incorporation onto the tablet.

THE SKIN MAP

What are the technology options for this? Does it need to be broken down or could it be presented as a whole body or video map. It is likely that patients will need to visit Aberdeen for this to be done. Some of Susan's findings from the interviews suggest that this aspect of the project will need to be handled sensitively, one patient reported that having the skin map formed was a humiliating experience. Patients suggested that they wanted to be able to mark any concerns directly on their skin maps. They wanted to able to zoom in to see the detail of the skin map and also to be able to move the photo around, i.e. to see the next body part using the touch screen.

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In consequence arrangements were made at Medical Illustration at University of Aberdeen for each patient to have digital skin map images taken. These were subsequently incorporated onto individual Google Tablets for individual patients.

THE REPORT FORM

The report back form should include options for labelling and a free-text box to explain the outcome, e.g. new mole, new spot, lump, no concerns etc. Patients preferred not to have the option to mark the report urgent – felt that this is something for specialists to decide. Previous report backs should be stored within the app for future reference

PROCESSES – "FLOWS OF INFORMATION"

LANGUAGE

Language used throughout should be chosen with care. In particular, when asking people to perform tasks language should be simple. For example, the term "Personal Skin Check" was perceived as more meaningful, understanding and less daunting to an individual than "Total Skin Self-Examination." Language needs to communicate what they are being asked to do; why they are being asked to do it; how to do it; what might happen when they do it; what the corresponding consequences and further actions of outcomes is.

TRAINING THE USER

Training eventual participants in the pilot exercise will be key.

The issue of engaging participants with the technology is important. The consensus from the plenary was that patients would be more likely to embrace the use of the technology if it was presented in conjunction with the benefits of using technology and the incentives listed about. (e.g. less travel, more control etc). It will also make sense to introduce the technology used as "just something used in healthcare." Patients can manage many much more complex activities and equipment than are being proposed here, for example nebulisers, home oxygen and glucose monitoring in diabetes.

The training must, however, show people how to do the intervention. As one specialist has pointed out one of the main purposes of follow-up appointments is to detect nodal disease. For this reason the individual participants should be shown how to examine their appropriate lymph node basins (neck, groins or axilla. These are practical skills that need to be demonstrated and can be reiterated on the video

However, it will be important not to make the assumption that people will manage to use the tablet/technology. Appropriate training will, and should be delivered. It will also be important to recognise that younger people may be more easily able to engage with the technology. Nevertheless there is a danger of making assumptions according to age stereotypes. We should aim for a standardised non-ageist way of introducing the technology and training people in the system. We should guard against training which is patronising and offensive to older people and too sketchy for younger patients leaving them less well informed.

REPORTING TO THE SPECIALIST

Several functions of the intervention are encapsulated within this step. In most cases patients will be feeding back negative findings. This will convey a sense of reassurance to them and

will, in effect, be the reward for performing the behaviour. In other circumstances a new lesion will be found. In this case, a decision on what is to happen will be available within 48 hours, much quicker than under existing systems. It is likely, therefore that both outcomes will reinforce the behaviour.

There were few concerns from patients about communicating information (including body images remotely). They would assume that security was in place. Technology experts offered "scrambling", "encryption and "cropping images" as further means to ensure security.

FEEDBACK FROM THE SPECIALIST

When the report (no concern) or issue arising is returned participants would want to receive a "report received" receipt. They felt this should be tailored to reflect how long it would take to get a response. It should also provide a phone number which could be contacted if the patient was concerned meantime.

514x386mm (180 x 180 DPI)

BMJ Open

Total skin self-examination at home for people treated for cutaneous melanoma: development and pilot of a digital intervention.

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Total skin self-examination at home for people treated for cutaneous melanoma: development and pilot of a digital intervention.

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ABSTRACT

Objectives: To develop a digital intervention to prompt, support and respond to the outcomes of total skin self-examinations (TSSEs) at home by people treated for cutaneous melanoma.

Design: A complex intervention development study

Setting: Northeast Scotland

Participants: Semi-structured scoping interviews; People previously treated for cutaneous melanoma (n=21). Pilot testing; people treated for melanoma stages 0-2C (n=20); general practitioners (n=6); and a nurse specialist in dermatology (n=1).

Intervention: A tablet-based digital intervention designed to prompt and support TSSEs comprising instructional videos and electronic reporting (including photographs) to a clinical nurse specialist in dermatology with subsequent clinical triage.

Primary and secondary outcome measures: Qualitative assessment of intervention feasibility and acceptability and quantitative assessment of intentions and confidence to perform TSSEs in pilot participants.

Results: The majority of pilot participants were strongly positive and adhered well to the intervention (n=15) with seven of these reporting symptoms of concern at some point during the six month pilot. Four patients complied intermittently, three reporting skin problems at least once during the pilot, and one withdrew. Two patients underwent skin surgery as a result of participating in the pilot, with one proving to have a recurrent melanoma, the other a benign lesion. A number of practical issues to improve the usability of the intervention were identified. The proportion of participants reporting intention to check their skin at least monthly increased during the intervention as did confidence to conduct a skin check.

Conclusions: People previously treated for cutaneous melanoma are prepared to use digital technology to support them in conducting total skin self-examination. An intervention has been developed which is practical, effective and safe and, after addressing minor practical issues, could now be evaluated for clinical outcomes in a randomised clinical trial.

ARTICLE SUMMARY

Article focus: We describe the development and feasibility testing of a complex, digitally supported, behavioural intervention to prompt, support and respond to regular total skin self-examination by people previously treated for cutaneous melanoma.

Key messages: A feasible and acceptable intervention has been developed. Participants in the pilot study adhered well and were highly positive about their experience of using the intervention. Preliminary evidence suggests that the intervention can help sustain regular total skin self-examination by people previously treated for cutaneous melanoma and lead to prompter resolution of concerns, and potentially early detection of recurrence.

Strengths and limitations of this study:

- The study involved key stakeholders and followed a well-evidenced and iterative approach to developing theory, devising an intervention and establishing its feasibility and potential efficacy in a real-world clinical environment.
- The pilot is small-scale which has implications about the representativeness of our participants. A randomised clinical trial is now required to inform wider implementation.

INTRODUCTION

People previously treated for cutaneous melanoma are at risk of recurrences and new primary melanomas.[1,2] The early detection of these events is one of the key aims of structured follow-up programmes for cutaneous melanoma and these are supported by guidelines in most countries.[1,3,4] Delivering effective structured melanoma follow-up to a growing population of eligible people is burdensome to health services.[5] Furthermore, many recurrences and new primaries occur in the intervals between structured melanoma follow-up visits.[1,6] In recognition of this, guidelines advocate that patients treated for cutaneous melanoma should be instructed to perform total skin self-examinations (TSSESs) and to conduct these examinations regularly in the intervals between structured follow-up visits.[1,4]

There are reasons to believe that such regular TSSESs performed by people previously treated for cutaneous melanoma could yield marked survival benefits.[7,8] For example, those who detect their own recurrences may have as much as a 63% reduction in mortality.[9] Furthermore, a review of the efficacy of skin self-examination for early detection of melanoma found evidence of high specificity (83% to 97%) for the detection of new lesions.[10] Sensitivity was lower but the included studies were not conducted with those previously treated for melanoma. It seems likely, although it cannot be stated with certainty, that a previous diagnosis of melanoma would increase knowledge and awareness with a corresponding increase in sensitivity. There is also some evidence, from a US case control trial and Australian modelling paper, that skin self-examination can reduce the development of advanced disease and facilitate early detection of recurrence by people affected by melanoma.[9,11] It is hoped that support to perform TSSEs could enable both recurrences and new primaries to be detected at an earliest stage when a cure may still be possible. The risk of recurrence in cutaneous melanoma is influenced by the stage of disease at

diagnosis.[11] Less intense follow-up regimens have been advocated for those with early stage disease at diagnosis (Stage IA, IB, IIA) and effective and sustained TSSEs could be particularly important in underpinning these.[11] Equally, however, since all patients treated for cutaneous melanoma are at risk of recurrence, effective TSSEs could be viewed as having a role as an adjunct in follow-up irrespective of clinical stage at diagnosis

Despite this, TSSEs education and practice appears suboptimal with 70% of American melanoma patients indicating that they have never been advised to do it.[12] We have found similar evidence of under preparation to conduct and performance of TSSEs in a UK population.[13]

Evidence from randomised trials suggests that people can be appropriately trained to conduct TSSEs.[14,15,16,17,18] However it is less clear whether TSSEs, once learned, can be sustained. Recent qualitative evidence suggests that the intention to conduct TSSEs wanes with time.[13] Digital technologies are becoming more prevalent in society, with a recent report that 49% of UK homes own at least one smartphone, tablet and computer.[19] More and more people are using personal electronic devices such as tablets and smartphones to obtain health information and to interact with healthcare providers.[20] This paper reports the development, pilot testing and preliminary evaluation of the Achieving Self-directed Integrated Cancer Aftercare (ASICA) intervention, a tablet computer based application designed to prompt and support total skin self-examination at home by people treated for cutaneous melanoma.

DEVELOPING AND PILOTING THE ASICA INTERVENTION

Overview

Our approach was based on the key development activities outlined in the MRC Framework for the development and evaluation of complex healthcare interventions.[21,22] Our developmental approach comprised a number of activities which:

Generated evidence on how technology has been used in cancer follow-up, how people with melanoma perceived this technology that could be used to support them to conduct TSSEs, and how to target technology at those patients with most potential to benefit.

Identified and developed theory grounded in Information Motivation Behaviour Skills (IMB) as an explanatory model combined with Control Theory and Implementation Intentions to underpin the theoretical development of the intervention.[23,24,25,26,27]. The IMB model proposes three requisites for engaging in preventive behaviours: individuals must have access to relevant information; be motivated to act; and be both capable and confident (self-efficacious) enough to carry out the behaviour in question . IMB has been used successfully to explain and change health relevant, preventive behaviours; for example an IMB based intervention was more effective than information alone in increasing HIV prevention behaviour (condom use) in truck drivers. [23,28]Control theory, first proposed in 1982, proposes that behaviour is maintained through monitoring and evaluation of the discrepancy between goals and current behaviour via a discrepancy-reducing feedback loop.[25,29,30] A specific goal (e.g. performing TSSE) is compared with current behaviour and if a discrepancy is detected, action is taken to bring behaviour closer into line with the goal. If the behaviour gets closer to the goal in response to feedback, the behaviour persists but if the discrepancy is perceived to be too great the individual may disengage from the behaviour. Interventions based on Control Theory are consistently shown to be effective in

changing health related behaviours in clinical and non-clinical populations.[31] For example, in a meta-regression examining interventions to change health-related behaviours in 122 studies, the most effective interventions included techniques based on Control Theory (self-monitoring goal setting, specify action goals, feedback and review of goals).[32] A third model used in the current study concerns 'implementation intentions' or 'action plans'.[26,27] Action Plans are short 'if-then' plans that have been shown to be effective in enabling individuals to achieve their behavioural goals in a wide range of contexts. Thus IMB theory proposes the factors needed to engage in a target behaviour - information, motivation and skills/confidence, and Control Theory and Action Plans indicate the processes necessary to keep the behaviour going (goal prioritisation, feedback, behavioural discrepancy detection), and the techniques that can be used to help individuals achieve and maintain target behaviours. Using these models the components for a potential intervention were theorized in consultation with experts in behavioural science, and the mechanism for the whole intervention to prompt, record and respond to TSSEs by patients in their own homes was conceptualized and implemented using Behaviour Change Techniques (BCTs).

Modelled the process of delivery of the combined components of the intervention. A major challenge to this project was to combine the theory and evidence-based components into a viable intervention and we used innovative methods to simulate the full intervention. This was done using an experience laboratory event facilitated by experts where healthy volunteers simulated the processes of the theorized ASICA intervention.

Once the prototype ASICA intervention had been developed we assessed the feasibility and acceptability of the prototype ASICA intervention (figure 1) through a pilot exercise with a group of patients supported by a nurse specialist in dermatology.

DEVELOPING THE ASICA INTERVENTION

Generating the evidence to use and target technology

Evidence was derived from three sources. First, a systematic review was conducted to determine how technology has been used to support people with cancer. The methodology and results of this systematic review are reported in detail elsewhere.[33] Second, interviews were conducted with 21 people previously treated for cutaneous melanoma. Full ethical approval for the interviews was sought from the North of Scotland Research Ethics Committee and granted on 2nd May 2012. The methodology and results of these interviews are reported in detail in a previous publication.[13] Third, clinical data were sought and obtained where available on recent recurrences and new primary melanomas diagnosed in Northeast of Scotland. The methods to obtain, analyse and interpret these data have been reported in detail.[6]

When integrated, this evidence suggests that the technology to deliver cancer follow up care remotely is available, safe and acceptable. Furthermore, people treated for cutaneous melanoma can see the benefit of conducting TSSEs but feel ill-equipped to perform it properly, safely, regularly and sustainedly. They can, however, see the potential of technology to support them in this endeavour and want to be shown how to conduct sequential TSSEs and then reminded when and how to do it. They also believe that this process could be supported by repeated reference to an instructional resource (e.g. a video) and self-reference (e.g. a digital skin map). Once they have conducted a TSSE they want to be able to report their findings quickly to a specialist and be reassured that the specialist would check their report and respond quickly if there were concerns. They would also welcome the potential opportunity to engage with healthcare professionals from their own homes without inconvenience (travel, time off work, parking). This was especially so for rural dwellers.

The evidence garnered from the literature and interviews also found that potential recipients strongly felt that approaches to monitor potential recurrence need to be developed carefully, and should not replace current hospital based follow-up until their safety and efficacy have been proven. The clinical data also suggested that recurrence is relatively common, occurs early and is usually found at the follow-up clinic within the first year. Therefore, an intervention to support TSSEs should be implemented within a month or so of diagnosis to afford maximum benefit.

Identifying and developing theory

The research team included an academic GP, a health services researcher, two health psychologists, and two computer scientists). Together, they had expertise in intervention development and evaluation, behaviour change and translating behavioural interventions into programmed computer applications. The chief investigator (an academic GP) first conceptualized the aims, processes and outcomes that the digital intervention should achieve. The final theoretical intervention was then produced in a series of three consensus meetings involving the whole research team.

The overriding aim of the intervention was to prompt the performance and reporting of good quality TSSEs by people previously treated for cutaneous melanoma. To achieve this, individuals must be shown how to use technology to conduct optimal TSSEs and then be prompted to conduct TSSEs regularly. They need to be able to remind themselves how to undertake TSSEs when they are due to do it. The intervention must then transmit the result of each patient's TSSEs to an overseeing clinician who will then respond appropriately (i.e. employ clinical triage) when a patient did identify a concern.

These aims, processes and outcomes were agreed at the first consensus meeting of the whole research team. Consideration was then given to the most appropriate theoretical model able to inform an intervention to achieve these aims, support the necessary processes and deliver the desired outcomes.

By consensus with the research team, it was decided that the Information-Motivation-Behaviour model offered the most promise in explaining current use of TSSEs.[23] Using this model the components for a potential intervention were theorized (i.e. components that would provide information about TSSEs, motivate individuals to perform TSSE and develop skills and confidence to perform TSSE) and the mechanism to prompt, record and respond to TSSEs by patients in their own homes was conceptualized. This is illustrated in figures 2a and b.[23,24]

At a second consensus meeting the results of the interviews conducted at stage A were considered. It was felt that, while the explanatory outline was based on the IMB, the results of interviews A indicated that, while patients required more information, they were already highly motivated and we therefore required a theory that guided the translation of motivation into action. The psychologists proposed that the process of the intervention should therefore incorporate Action Planning and should be revised to be additionally guided by 'Control Theory' as this theory deals with the process of self-regulation to change behaviour from a pattern that fails to achieve the person's goal to one that achieves their goal.[23,24,25] Together, these theories outline the process of change and give some guidance on the behaviour change techniques (BCTs) (i.e. the active ingredients that make up an intervention and are required to change behaviour) which the intervention required.[34] Some techniques were required to develop the knowledge and behavioural skills to enact the behaviour (e.g. demonstrating the behaviour, rehearsing/practising TSSEs), some to enhance/maintain the

person's motivation to engage in the process of TSSEs (e.g. providing information on health consequences of the behaviour (TSSEs), using a credible source for the information), some to enhance confidence that they could conduct TSSEs successfully (e.g. mastering the skills necessary), and some to enable self-regulation of action, especially remembering when to act (e.g. prompts and cues) and the sequence of actions necessary for the optimal clinical outcome (e.g. Action Planning, where patients who have decided to do TSSEs would make a clear plan when, where, and how they would do the examination). Planning 'how' to perform TSSE might include involving someone else (e.g. to examine areas of skin that they cannot easily see themselves), and planning 'when' to receive a reminder. In addition, some techniques were designed to maintain continued engagement in the behaviour (e.g. receiving feedback)[26,27].

To produce the final theoretical intervention a final consensus meeting was held. The whole research team first discussed the fidelity of the theory to the delivery of the intervention, and then worked together to map a theoretical structure for the intervention, incorporating the identified BCTs where appropriate. The intervention demonstrated the target behaviour (with a video clip); enhanced motivation to perform TSSE (with recorded information about the consequences of performing/not performing TSSE); enhanced confidence (with the incorporation of step by step instructions and opportunities to try each step into the video clip). The intervention tackled the issue of intentional and non-intentional non-adherence (including forgetting, deferring, avoidance or deciding it is unnecessary) (using cues to prompt individuals to undertake TSSEs); provided individuals with feedback about the behaviour (by sending TSSE results to health professionals and having the professional reply); and checked adherence to TSSE (by asking individuals to mark skin maps/record how long the personal skin check took). This gave an indication of thoroughness and provides information on those who do it more quickly because, for example, they have other

commitments, or those who choose to adopt avoidance. This allows the monitoring of adherence and engagement. A strategy to identify avoidance is very important since, without it, clinicians could be making clinical decisions and providing clinical advice based on incorrect information.

Modelling the process of delivery of the intervention

Experience laboratory event

An Experience Laboratory event was held in May 2013 at Glasgow School of Art's Centre for Design Innovation, in Forres, Moray.[35] This facility enables the creation of different environments to simulate real-life situations. The processes of delivery for the ASICA intervention, including simulation of the clinical sequences, were developed for use at the event. This included a simulation of the information and TSSEs demonstration for a potential supporting digital application, which was produced and embedded upon a hand-held tablet computer, with guidance from experts in design and presentation. Three locations were constructed: a patient bedroom **[Photo 1]**, a GPs surgery, and a clinical nurse specialist's office, the latter two being equipped with video-conferencing capability. The intervention components included in the simulation were: the cue to action (i.e. the prompt to complete TSSEs); the instructional video (showing how to conduct TSSEs); the skin-map (to be used while conducting TSSEs) and the report sent to health professionals (following completion of TSSEs).

The Experience Laboratory event was facilitated by design experts and attended by five patient volunteers (one supported by a helper) unaffected by cutaneous melanoma who performed a simulation of the theoretical intervention (as shown in figure 2b), a GP, a clinical nurse specialist in dermatology and the researchers.

Following an initial briefing session an existing instructional video produced by MASCOT (Melanoma Action and Support Scotland) describing how to conduct TSSEs was viewed by all participants. Two scenarios were constructed and enacted by each of the patient volunteers. In the first, the volunteers were asked to perform TSSEs at which no problems were detected. In the second scenario, the volunteers conducted TSSEs at which a new mole was detected. In this latter scenario the patient attended the GP surgery location for a video consultation between themselves and the co-located GP, and the remote clinical nurse specialist.

A professional TV company filmed and edited a video of the proceedings. At the conclusion of the day all participants viewed the video and a feedback and a debriefing session was held.

Integrating components and processes of the ASICA intervention

The Experience Laboratory enabled participating stakeholders to articulate and agree the benefits which the ASICA intervention could deliver to recipients. Furthermore, the activity enabled the theoretical components of the intervention to be operationalized in the simulation in order to gain insight into how well they integrated and served the purposes for which they were intended i.e. to support the mechanism of prompting, recording and enabling a response to TSSEs. The Experience Laboratory also enabled the researchers to gain insight into the detailed processes and the sequence in which they should occur to support the effective operation of the ASICA intervention. These were: the language used; training of the user; reporting to the specialist, and receiving feedback from the specialist. The detailed learning achieved on each component is also summarised in appendix 1.

Combining processes and components in a prototype intervention

As a result of the Experience Laboratory event, the detailed components and processes identified and developed during the theoretical stage were integrated into a prototype ASICA intervention, including a supporting digital application which was designed to run on a Google Nexus 7 tablet computer. Distinct from the application were several other components including:

1. The structured training session required at inception.

2. The initial and recurring cue to action required to remind the patient to conduct a personal skin check. The need for this to be a separate trigger (sent by email or text message to the recipient's mobile phone) was necessary to avoid the risk that the tablet was used only for skin checks with the risk that the prompt would not be received.

3. The specialist response, a telephone call from the overseeing specialist nurse within 24 hours, since both the human contact and immediacy were perceived as important reassuring factors when a patient could be anxious.

Based on the Experience Laboratory findings, the prototype intervention was adjusted for piloting. The need for clear and simple language unifying the application and supporting processes was perceived to be key to user engagement and intervention adherence. Within the digital application, language was made consistent with the language introduced at the training session. This was carried over into an animated instructional video which was produced and divided into chapters based upon body areas and used as a means to demonstrate and remind users about the specific behaviours required to check their body. Conducting the personal skin check using the application was designed to follow a logical sequence supported by a check-list for self-monitoring of completion. The process of feeling for lumps in regional nodal areas was routed so that only the appropriate nodal area was examined by each patient.

Patients are also able to check an integrated individualized skin-map (formed of a series of professionally produced clinical photographs of each patient) to determine whether skin lesions were new or changing. This function was further supported by the application storing previous reports/images for future reference. At the conclusion of the skin-check the ASICA application delivers a message that either no problem has been reported, or in the event that a symptom concern has been raised, that a specialist will be in touch within 48 hours with further advice. In either eventuality, the completion of the TSSEs is recorded and acknowledged giving a sense of completing the processes in a way that provides feedback and reassurance; this acts as a reward for completing the behaviour with the aim of reinforcing the behaviour so that individual patients will keep using the ASICA application.

PILOT STUDY OF THE FEASIBILITY AND ACCEPTABILITY OF THE PROTOTYPE ASICA INTERVENTION

The prototype ASICA intervention, including the supporting digital application, was subject to a pilot study of feasibility and acceptability amongst 20 people who had previously been treated for cutaneous melanoma. Full ethical approval for the pilot study was sought from the North of Scotland Research Ethics Committee and granted on 10th June 2013

Recruitment

Six practices were purposively selected to represent geographical spread within the NHS Grampian region of Scotland, and a GP from each was invited to a training meeting to have the protocol explained. The lead GP at each practice identified and approached potential participants for pilot study. Eligible patients were aged over 18, had been diagnosed and treated for cutaneous melanoma within the preceding five years, were currently receiving hospital-based follow-up, and had no nodal involvement or metastases (i.e. in-situ to stage 2C). The 20 people agreeing to participate were identified to, and approached by, the research

team. The characteristics of participants are shown in table 1. Recruits attended the Medical Illustration department at the University of Aberdeen to have a full personal body mapping digital photography taken. These were subsequently hosted on a secure server and could be accessed by individual patients to refer to during subsequent skin checks.

Participant training

Three training sessions (each of two hours duration) were held in Aberdeen. The meetings followed a structured programme. Participants were introduced to the study and its purposes. The fact that the intervention was experimental (and additional) to their ongoing follow-up was stressed to ensure default from follow-up was not suggested. Participants were instructed in the use of the application and tablet, including how to access their digital skin maps, and their understanding and ability to comply checked. Patients were given detailed instruction manuals for both the tablet and the application. The project researcher arranged an individual meeting with one individual that was not able to attend the training sessions. To prepare for a future clinical trial a questionnaire was modified, with permission, from one used previously.[15,16,17] The questionnaire (included as appendix 2) sought information about respondents' skin cancer history, their skin self-examination practices and intentions, their attitudes, beliefs, self-efficacy and intentions about conducting skin self-examination, the Hospital Anxiety and Depression scale, information about comorbidities and their demographic characteristics. Participants were asked to complete the questionnaire upon arrival at their initial training session. They were then sent the questionnaire again at the conclusion of the pilot.

Pilot study process

Participants were sent a monthly email reminding them that it was time to conduct their personal skin check. Upon receipt of the reminder it was intended that they would use the

ASICA application to help them systematically examine their skin and through the application they were able to view the integrated instructional video chapters to enable them to do this. A structured electronic report pro-forma was available for completion. Where a new lesion was identified either at the previous melanoma site or a new one, participants were able to complete a free-text description and/or attach a photograph taken using the tablet's camera function. Completed reports were then sent electronically to a secure and remote server. The returned reports were communicated to, and reviewed by, an overseeing nurse specialist. Figure 1 illustrates the TSSEs procedure supported by the ASICA application. Where patients had identified concerns they were contacted by telephone within 24 hours by the reviewing nurse specialist who either provided reassurance or invited them to an upcoming clinic for subsequent review. At the conclusion of the pilot study all continuing participants were invited to attend for a total skin examination at their GP surgery and 15 accepted this invitation and attended. Three declined, one because he has regular private skin checks, one because he was on holiday at the time of the appointment, one because he was undergoing treatment for metastatic melanoma, and one did not attend.

At the conclusion of the pilot the project researcher SH contacted all participating patients and the overseeing clinical nurse specialist to conduct a brief telephone interview. These interviews aimed to capture the practical experiences and personal reflection of participants in the pilot study. They were conducted to identify participants' perceptions of strengths and weaknesses with the components, or the process and delivery of the intervention, so that subsequent improvements could be made. The interviews were guided by a topic schedule. Questions focused on patients' perceptions of the strengths and weakness of the ASICA application and how it had functioned. The interviewer also gathered information about how well the technical aspects of the intervention had worked from the nurse-specialist and patient

perspective. The interviews were conducted by telephone and were recorded and transcribed for subsequent analysis and reflection by the research team.

As this was a pilot study no *apriori* hypotheses were determined based on clinical or psychological outcomes. We did, however, ask participants to complete a questionnaire seeking information about clinical, behavioural and psychological outcomes to aid preparation for a subsequent clinical trial.

Pilot study results

a) Feasibility

Details of the number and regularity of the skin checks participants performed during the pilot can be seen in table 2. Of the 20 participants, 15 complied well and eight reported no symptoms during the six-month pilot, seven reported at least one issue to the overseeing clinical nurse specialist. Most issues were resolved by submitting further images under the direction of the specialist nurse, with a corresponding telephone call. Two participants subsequently had the lesions spotted during personal skin checks removed, one was a recurrent melanoma and the other was a benign lesion. Of the three less compliant participants one regularly checked only his face where his original primary had been, another checked selected areas less regularly, citing work pressures and lack of time to conduct TSSEs. Another, a busy mum who stated she found it difficult to make time to conduct a TSSEs, checked their skin only once, on that occasion reporting three issues of concern to the overseeing nurse specialist. One participant withdrew for undisclosed personal reasons.

With respect to the technical operation of ASICA the nurse specialist stated that on the few occasions when photographs of new skin lesions had been submitted by participants these were typically of insufficient quality on which to base clinical judgements. However, in

almost all cases he was able to contact the patient and direct them to take improved images. As a result guidelines to take good quality images have been incorporated into the revised app.

b) Acceptability

Patients were largely positive about their experience of using ASICA. The user-friendliness of ASICA was highlighted, along with views that participation supported good habits, allowed participants to become familiar with their own bodies, and provided them with empowerment and reassurance. Table 3 describes comments which reflect these themes. Technical issues raised by patients fell into three categories. There were minor issues with the interface (e.g parts of electronic buttons being obscured) which have been modified. Some patients, especially those in the more remote rural areas, were troubled by issues related to their internet connection. These are less easy to resolve but are likely to be more common in this particular geographical location than in the majority of the rest of the UK. Government initiatives and technological advances will help going forward in this regard. Similarly, there were some issues with the hardware, for example a malfunctioning charger in one case and a damaged screen in another.

c) Piloting trial procedures

Sixteen participants completed and returned the questionnaire at baseline and outcome. The data are not presented in detail. There were non-significant increases in the proportion of respondents indicating that they intended to check their skin at least monthly, and in the proportion indicating that they would be confident to perform total skin self-examination. No significant changes were observed between baseline and outcome in anxiety, depression or cancer worry. These data will however, be informative in determining power for a subsequent randomised trial.

DISCUSSION

Principal findings

The authors have developed a feasible clinical intervention process based on a digital tablet-based application to prompt, record, and respond to regular total skin self-examination by people previously treated for cutaneous melanoma. This has proven to be acceptable and safe for patients to use. There is also preliminary evidence that it can help reinforce and sustain TSSEs in a way that has not previously been possible. Further, there is some early evidence that it can bring new skin problems to medical attention sooner than would otherwise have been the case. It must also be noted however that the fact that a minority of patients did not comply, or complied only partially, indicates that ASICA will not compel all patients to conduct regular TSSEs or might require tailoring for some patients.

Strengths and limitations

Strengths

The approach adopted for developing the ASICA intervention had several inherent strengths. Developing interventions that employ digital technologies to deliver aspects of healthcare in a completely new way is immensely challenging. For this reason our approach benefited from employing the structured, iterative and well-rehearsed approach advocated by the MRC framework.[21,22] The use of the Experience Laboratory allowed simulation of the complete intervention, integrating components based on theory and evidence. The experience of the team in following this approach and the strong theoretical underpinning of the IMB and Control Theory models allowed the project to be phased and focused.[23,24] We involved key stakeholders – potential patients, clinicians, technology specialists, behaviour change intervention specialists, health service researchers – at each stage of the process so that their perspectives were identified and incorporated throughout. Furthermore, adopting this multidisciplinary approach enabled an ongoing understanding of the full spectrum of

potential challenges and caveats which the intervention was required to overcome, complemented by an ability to exploit the enablers perceived by each group. We were also able to ensure that we optimised the potential of the ASICA digital application, identifying the necessary processes and components, and ensuring that they were developed and embedded within the intervention in the most effective way.

Limitations

Some limitations must be acknowledged. The pilot was conducted on a small scale within Northeast Scotland. Clearly, this has implications about the representativeness of our participants. In terms of the whole Scottish population they were relatively affluent and also willing to learn about technology. It was assumed that all patients were physically capable of using the tablet and the application, but one could not use their fingers and required to be supplied with a stylus. There were other disabilities that were not provided for, for example poor eye-sight, lack of proficiency in English and restricted physical movement. A range of adherence was observed during the study and we were unable to understand this in detail. ASICA, as currently configured, will not suit everyone, but it may be possible to tailor it to individual need. While the developed intervention may have greater value and relevance among people familiar with technological advances and in localities where the clinical service is delivered to patients living remotely from the clinical centre, it is likely to have utility among a broad range of patients after melanoma diagnosis and treatment. This view is supported by noting that people with melanoma from stage 0-2C were willing to take part.

These limitations must be viewed against the backdrop of societal trends to embrace modern technology, and an increasing appetite amongst clinicians and policy makers to diagnose and manage skin cancer using digital means. A recent review, for example identified 40

applications of divergent quality and developmental rigour, for monitoring and diagnosis of pigmented skin lesions.[36]

Context with other studies

Where interventions have been specifically developed to improve TSSEs practice, and subjected to randomised trial the results have been disappointing, although the recruited patient groups have been different to this pilot study. Two randomised trials, one in a general US primary care population and another in Australian men over 50 at increased risk but with no previous melanoma, educated using brochure or video demonstrations only, reported increased TSSEs practice for 3-7 months, with participation returning to baseline after one-year.[14,15,16,17] A further study, employing a nurse or physician delivered an educational module supported by a personal skin map to US patients but referred to a secondary care pigmented lesion clinic, reported significant increases in TSSEs practice at 4 months.[18] Previous trials are informative to the current intervention for three reasons. First, all three were conducted in patients at increased risk, rather than patients actually treated for melanoma. It is therefore likely, that the target group of the ASICA intervention will be more motivated to conduct and sustain TSSEs than previously studied groups. Second, previous intervention development provides evidence that several of the components developed using health psychology-based approaches and incorporated into ASICA (such as the instructional videos, personal skin maps, cues to action and sample photographs) have the potential to promote and sustain, at least in the short-term, TSSEs in patients who form a lower risk group than the ASICA target population.[14,15,16,17,18] Third, and perhaps most importantly, the interventions previously trialled have comprised one-off educational activities with the issue of videos, booklets or brochures to patients for subsequent personal use.[14,15,16,17,18] ASICA, on the other hand, will use familiar everyday technology to prompt and sustain the

behaviour over time, in participant's own homes which should increase the likelihood of success.[37]

Lessons learned from this study

Evidence for components of previous interventions that have sustained TSSEs in the medium term has been translated onto a theoretical intervention based on well-evidenced theoretical models using the Behaviour Change Techniques Taxonomy v1 to implement the active behaviour change mechanisms.[34] We have learned that a skilfully facilitated experience laboratory can be used to provide rapid feedback on a theoretical and simulated intervention prior to its initial development and testing in a full-scale pilot trial. Finally, we have used carefully assembled theory and knowledge to build a working proto-type of an actual digital intervention to support TSSEs by people previously treated for cutaneous melanoma. This has functioned well in a real world pilot. It has succeeded in actually supporting, and responding to TSSEs, in a group of patients, who have appreciated and enjoyed using it. We have learned that it is a feasible and desirable intervention. We have also learned about the minor modifications that are required to proceed to a definitive clinical trial employing the ASICA intervention. Such a trial, conducted at several UK centres to ensure wider applicability, should now follow shortly, so that we can consolidate the promising findings reported here with definitive evidence of ASICA's role in future melanoma follow-up.

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CONTRIBUTORS

PM conceived the original intervention. SH conducted the initial exploratory interviews. The theoretical intervention was mapped by PM, SH, MJ, JA and translated into a working prototype by JM and MD, with advice on national implementation potential from FW. JM and MD developed the patient training sessions and materials, and the training was delivered by PM, JM, MD and SH. BB delivered the intervention. PM, SH, MD and FW generated and analysed the data. PM wrote the manuscript with contributions from all authors.

COMPETING INTERESTS

All authors have completed the Unified Competing Interest form at www.icmje.org/co_disclosure.pdf (available on request from the corresponding author) and declare that (1) None of the authors have support from any commercial company for the submitted work; (2) PM, JA, BB, MD, SH, JM, FW and MJ have no relationships with any commercial company that might have an interest in the submitted work in the previous 3 years (3) their spouses, partners or children have no financial relationships that may be relevant to the submitted work; and (4)) PM, JA, BB, MD, SH, JM, FW and MJ have no non-financial interests that may be relevant to the submitted work.

ETHICS APPROVAL

Full ethical approval for the interviews with people previously treated for melanoma study was granted by the North of Scotland Research Ethics Committee on 2nd May 2012. (REC reference number: 12/NS/0039). Full ethical approval for the pilot study was granted by the North of Scotland Research Ethics Committee on 10th June 2013. (REC reference number: 13/NS/0062)

STUDY SPONSOR

The University of Aberdeen is the study sponsor. PM, JA, MD, SH, JM and MJ are employees of the University of Aberdeen but all researchers were independent from the sponsor and funders in study design, the collection, analysis and interpretation of data, the writing of the article and the decision to submit for publication.

DATA SHARING STATEMENT

Process data about how ASICA performed during the pilot exercise and which does not identify patients, along with the technical specifications of the ASICA digital application may be available upon application to the corresponding author.

FIGURE LEGENDS

Figure 1: TSSEs Procedure as Supported by the ASICA application

Figure 2a: Model demonstrating theoretical processes of ASICA according to Information-Motivation-Behaviour Skills (IMB) model – adapted from Cowling et al, 2011

Figure 2b: Schematic demonstrating operationalization of components and processes of ASICA intervention adapted from Cowling et al, 2011.

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Table 1: Characteristics of pilot study participants

ID	Age	Gender	Place of Residence*	Date of Mel Dx	Site	Stage
001	46	F	Accessible rural	2010	Arm	1.1mm Stage 1B
002	49	F	Other urban area	2012	Knee	0.5mm Stage 1A
003	72	F	Accessible rural	2013	Arm	0.4mm Stage 1A
004	69	M	Urban	2013	Breast	0.8mm Stage 1A
005	62	M	Remote rural	2012	Eyelid	M in situ Stage 0
006	66	F	Remote rural	2011	Cheek	0.3mm Stage 1A
007	72	M	Remote small town	2009	Cheek	2.8mm Stage 2A
008	70	M	Remote small town	2012	Shoulder	0.3mm Stage 1A
009*	41	F	Remote rural	2011	Back	>1mm
010	67	F	Accessible rural	2009	Arm	3mm Stage 2A
011	78	M	Remote small town	2008	Eyebrow	2.6mm Stage 2A
012	42	F	Accessible small town	2011	Back	M in situ Stage 0
013	75	F	Accessible rural	2009	Thigh	1.1mm Stage 2B
014	67	M	Accessible rural	2013	Shoulder	2mm Stage 2A
015	46	F	Accessible rural	2011	Abdomen	0.6mm Stage 1A
016	72	M	Accessible rural	2011	Forearm	1mm Stage 1B
017	65	M	Accessible rural	2014	Shoulder	M in situ Stage 0
018	69	M	Remote rural	2009	Shoulder	1.5mm Stage 1B
019	44	M	Accessible rural	2012	Abdomen	1.5mm Stage 1B
020	44	F	Accessible small town	2010	Lower leg	0.42mm Stage1A

Classifications from Scottish Government Urban-Rural Classification[38]

*Staging data were not available for this patient

Table 2: Compliance with intervention and outcome of monthly skin checks

Patient	Month 1 (May)		Month 2 (June)		Month 3 (July)		Month 4 (August)		Month 5 (September)		Month 6 (October)	
	Number of body areas checked	Changes reported	Number of body areas checked	Changes reported	Number of body areas checked	Changes reported	Number of body areas checked	Changes reported	Number of body areas checked s	Changes reported	Number of body areas checked	Changes reported
N=8: Complied well, reported no symptoms												
P02	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**
P03	**0**	**0**	**0**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**0**	**0**
P04	**5**	**0**	**5**	**0**	**5**	**0**	**0**	**0**	**0**	**0**	**5**	**0**
P05	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**
P06	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**
P10	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**
P16	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**
P19	**5**	**0**	**0**	**0**	**5**	**0**	**0**	**0**	**5**	**0**	**5**	**0**
N=7: Complied well, reported symptoms												
P01	**4**	**1**	**0**	**0**	**5**	**2**	**5**	**2**	**4**	**1**	**5**	**0**
P07	**5**	**3**	**5**	**5**	**5**	**2**	**5**	**0**	**5**	**2**	**5**	**0**
P08*	**4**	**0**	**5**	**0**	**5**	**0**	**5**	**2**	**5**	**0**	**5**	**1**
P13	**3**	**3**	**1**	**1**	**5**	**0**	**5**	**0**	**5**	**0**	**5**	**0**
P14	**0**	**0**	**3**	**2**	**4**	**0**	**5**	**1**	**5**	**0**	**4**	**0**
P15	**5**	**1**	**0**	**0**	**5**	**1**	**5**	**0**	**5**	**0**	**5**	**0**
P18* **	**5**	**1**	**0**	**0**	**5**	**0**	**0**	**0**	**5**	**1**	**0**	**0**
N= 3: Complied less well, reported symptoms												
P11**	**1**	**1**	**1**	**1**	**1**	**0**	**1**	**1**	**1**	**1**	**1**	**1**
P12	**0**	**0**	**1**	**0**	**0**	**0**	**3**	**1**	**0**	**0**	**0**	**0**
P17	**0**	**0**	**0**	**0**	**3**	**3**	**0**	**0**	**0**	**0**	**0**	**0**
N=1: Complied poorly, reported no issues (P20												
P20	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**5**	**0**	**0**	**0**
P09	**PATIENT WITHDREW CITING PERSONAL CIRCUMSTANCES MAKING SKIN CHECKS DIFFICULT – NOT CLEAR WHAT THESE WERE**											

*P8 diagnosed with recurrent melanoma after excision of lesion noticed during personal skin check

**P11 checked head and neck only

***P18 diagnosed with benign lesions on both legs after excision of lesions noticed during personal skin check

Table 3: Comments from patient interviews reflecting views on usability and acceptability

A USER FRIENDLY DEVICE P03 – "Yes, it was quite clear the actual information that we were given, very clear, beautifully set out, very easy to use and understand. P04 – "Very good. Very good indeed. It's very clear, easy to understand and useful in tips about parting your hair and getting somebody else to check the back of it for you and things like that, yeah, very clear and easy to understand and you know, tips about how to do awkward places on yourself, yes. P05 – "So what I've done is have a good look at myself over the preceding days, if you know what I mean, just as and when it was comfortable. And really handy, when I was getting changes, getting up or going to bed or what have you, in the shower. And then just rattle through the app. P08 – "The animations that were provided I thought were a really good guide, for somebody that's not used to technology it was really simple." P17 – "Well it tells you exactly what you need to know, there's no question about that." P21 – "The instructions were excellent, they were very well laid out. The videos were very helpful showing you exactly what you needed to do and how to check yourself all over."
ESTABLISHING GOOD HABITS P04 – "But the fact that it makes people do it once a month or whatever, it focuses the attention because it's something we'd probably be a bit slapdash with normally." P13 – "The tablet is great. Totally self-explanatory and the videos are very easy to watch and everything so it very easy to do and send off the report. Everything was great." P15 – "It made you really thorough about the skin check procedure. There was no way you could miss anything out. It was really good." P16 – "Yes, as I say, it's all clear and it's really good to see every part of your body…to go through it all in separate stages. Yes, it make you do it all in a through way, which is important, since I'm not getting checked at the hospital anymore, so it's really important that I've got to remember to check my whole body in case something appears."
GETTING TO KNOW MY OWN BODY P01 – "I like having the maps to look at because I've got a lot of moles but I have discovered there might be a blind spot on my arms where it's not really getting my arm – if you know what I mean? P15 – "Without this it becomes very difficult to remember if anything has changed very much since the last time you looked. This was really the first time I've ever looked really closely at my body, and I think to myself "goodness, I didn't realise I have that there before." And then I go back to the body map and – which is a salutary exercise in itself - and see "oh yes, it was there." I suppose it's getting to know your body much better." P17 – "I never used to think about it, but I know what to look for now. If I see something I know what it is, and what to do. Before, I never would have noticed." P21 – "The more I've done it over the period of months, the more that I've gotten used to where everything is on my body, where all the different moles are." P21 – "Before starting this project I probably wasn't really checking my skin that much at all, but since I've been doing this, it's been much more regular and I've been paying much more attention to it.
FEELING REASSURED AND EMPOWERED P09-"I'm very pleased with it, because it's helping me, you feel in control, that you are looking after yourself." P12 – "If somebody is checking it, that can get back to you really quickly, then off to the GP. Very re-assuring." P14 – "And because I was doing it so diligently, I felt good about that." P14 – "It a brilliant idea, especially for people who are a long way away, because you can do a really thorough check, and received professional reassurance without having to travel all the way to Aberdeen."

Figure 1: TSSEs Procedure as Supported by the ASICA application

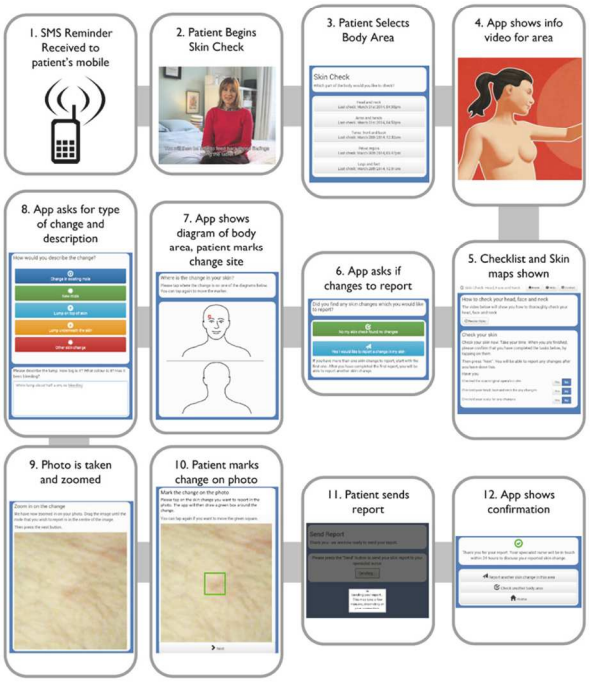
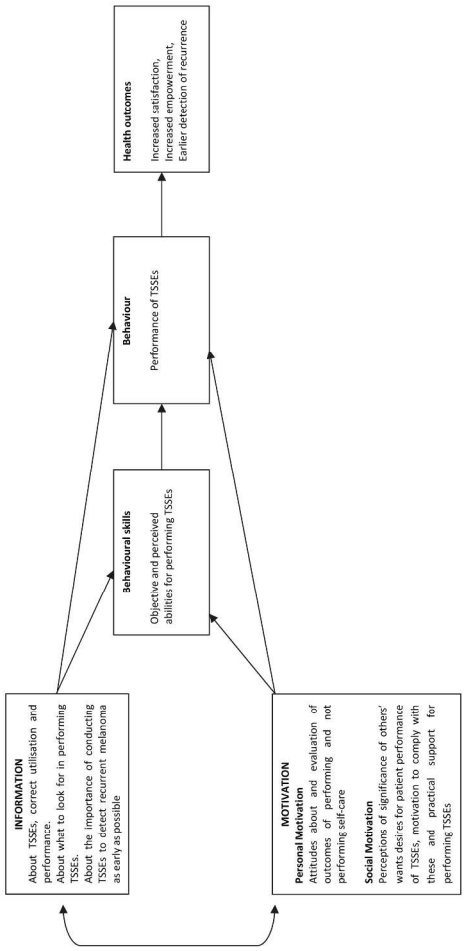


Figure 1
209x297mm (300 x 300 DPI)



1

Figure 2a: Model demonstrating theoretical processes of ASICA according to Information-Motivation-Behaviour Skills (IMB) model – adapted from Cowling et al, 2011.

Figure 2a
209x297mm (300 x 300 DPI)

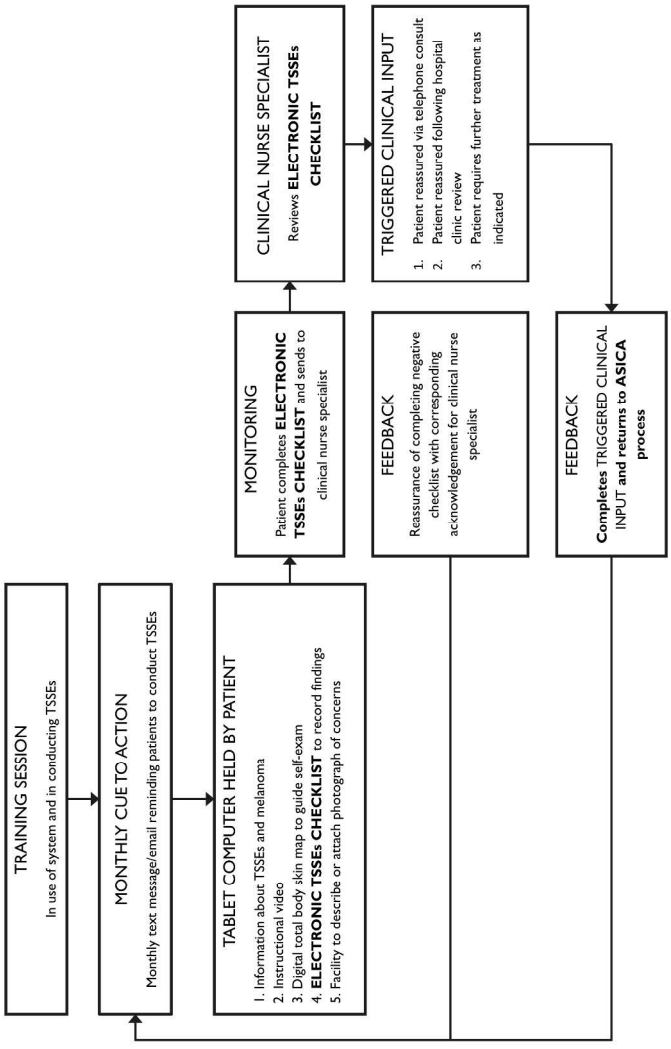


Figure 2b: Schematic demonstrating operationalization of components and processes of ASICA intervention adapted from Cowling et al, 2011.

Figure 2b
209x297mm (300 x 300 DPI)

Digitally supported total skin self-examination at home for people treated for cutaneous melanoma: developing and simulating experience of the ASICA intervention. Murchie et al

Appendix 1

This appendix displays the outcome questionnaire developed for use in a proposed future clinical trial of the ASICA intervention. It has been adapted, with permission from an instrument developed by Professor Monika Janda, Queensland University of Technology, Brisbane QLD, Australia. A related baseline questionnaire has also been prepared.

Janda M, Baade PD, Youl PH, Aitken JF, Whiteman DC, Gordon L, Neale RE. The skin awareness study: promoting thorough skin self-examination for skin cancer among men 50 years or older. Contemp Clin Trials 2009,31:119–130

Janda M, Neale RE, Youl P, Whiteman DC, Gordon L, Baade PD: Impact of video-based intervention to improve the prevalence of skin self-examinations in men 50 years or older: the randomized skin awareness trial. Arch Dermatol 2011, 147:799–806.

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UNIVERSITY OF ABERDEEN

ASICA Questionnaire (Outcome)

Achieving Self-directed Integrated Cancer Aftercare

All the information that you provide in this questionnaire is confidential. You cannot be identified from any of the answers that you give.

If you have any questions regarding this questionnaire please contact:

For official use only

dot.rural
Transformation through Digital Innovation

Date returned	
Date entered	
Date checked	

What is the purpose of this

questionnaire?

The purpose of this questionnaire is to find out some things about you, your melanoma and your general health.

What if I am not sure how to answer some questions?

Do the best that you can.

Should you have any difficulties with completing the questionnaire, or have any questions about the study please contact:

How long will it take to complete?

It should take no longer than 20 minutes to complete.

Is the information confidential?

All the information that you give is extremely valuable to the study and is treated in the strictest confidence.

What should I do with my completed questionnaire?

After you have filled in the questionnaire please put it in the addressed FREEPOST envelope provided and post it back to us. NO POSTAGE STAMP IS REQUIRED

We would be very grateful if you could return your completed questionnaire as soon as possible.

Thank you

Skin Cancer History

1. **Have you ever had a skin cancer, mole, or other spot/s removed or treated?**

☐ 1 Yes

☐ 2 No → Go to Q4

☐ 3 Unsure/Don't Know → Go to Q4

2. **How many skin cancers, moles, or other spots have you had treated?**

☐ 1 One ☐ 4 Eleven to twenty

☐ 2 Two to five ☐ 5 Twenty-One to fifty

☐ 3 Six to ten ☐ 6 More than fifty

3. **How old were you when you had your first skin cancer, mole, or other spot treated?**

☐ Do not remember

☐ Years old

4. **Are you currently concerned about a spot or mole?**

☐ 1 Yes ☐ 2 No ☐ 3 Not sure

5. **How likely is it, do you think, that you will get skin cancer again at some time in the future?**

☐ 1 Not at all likely

☐ 2 Somewhat likely

☐ 3 Very likely

☐ 4 Don't know/not sure

Skin Self Examination

6. Have you or someone who is not a doctor or nurse, such as your spouse or partner, ever deliberately checked any part of your skin for early signs of skin cancer.

☐ 1 Yes ☐ 2 No → Go to Q13

☐ 3 Don't know → Go to Q13

7. In the past 12 months, have you or someone who is not a doctor or nurse , such as your spouse or partner, deliberately checked any part of your skin for early signs of skin cancer.

☐ 1 Yes ☐ 2 No → Go to Q13

☐ 3 Don't know

8. In the past 12 months, how often have you or someone who is not a doctor or nurse checked any part of your skin for early signs of skin cancer?

☐ 1 One to two times ☐ 3 Five to six times

☐ 2 Three to four times ☐ 4 More than six times

9. In the past 6 months, how often have you or someone who is not a doctor or nurse checked any part of your skin for early signs of skin cancer?

☐ 1 One to two times ☐ 3 Five to six times

☐ 2 Three to four times ☐ 4 More than six times

☐ 5 Zero

10. Thinking back to the last time you or someone who is not a doctor or nurse checked your own skin, which areas of your body did you actually check?

☐ 1 Face ☐ 8 Feet

☐ 2 Neck ☐ 9 Back of thighs/knees/shins

☐ 3 Upper Chest ☐ 10 Bottom

☐ 4 Arms ☐ 11 Lower Back

☐ 5 Hands ☐ 12 Higher Back

☐ 6 Torso ☐ 13 Back of Neck/Scalp

☐ 7 Front of thighs/knees/shins ☐ 14 Whole Body

11. During your last check, did you use a handheld mirror or full-size mirror to check difficult to see areas of your skin such as your back?

☐ 1 Yes, hand-held mirror ☐ 4 No

☐ 2 Yes, full-size mirror ☐ 5 Don't know

☐ 3 Yes, both

12. During your last check did you have someone to help you see difficult to see areas for example your wife, partner or another relative?

☐ 1 Yes ☐ 2 No ☐ 3 Don't know

13. In the next 12 months, how many times do you intend to check your skin for early signs of skin cancer?

☐ Please write the number in the box.

We would now like to know *how confident* you are about being able to check your skin. Please *circle the number* that best describes your level of confidence for each of the following four questions.

14. How confident are you that you can check your own skin correctly?

1	2	3	4	5	6	7	8	9	10
Not at all Confident				Moderately Confident					Highly Confident

15. How confident are you that you will find the time in the next 12 months to check your own skin.

1	2	3	4	5	6	7	8	9	10
Not at all Confident				Moderately Confident					Highly Confident

16. How confident are you that you will remember to check your own skin at least once a month.

1	2	3	4	5	6	7	8	9	10
Not at all Confident				Moderately Confident					Highly Confident

17. How confident are you that if you find a spot or mole of concern that you will take appropriate action.

1	2	3	4	5	6	7	8	9	10
Not at all Confident				Moderately Confident					Highly Confident

18. When you last checked your own skin, did you find a spot or mole of concern?

☐ 1 Yes → → Go to Q19

☐ 2 No → → Go to Q21

☐ 3 Don't know/unsure → Go to Q21

☐ 3 Did not check my skin → Go to Q21

19. If yes, what did you do?

☐ 1 Watched it for up to one month

☐ 2 Watched it for longer than one month

☐ 3 Showed it to partner/relative

☐ 4 Showed it to a doctor/nurse

☐ 5 Other, please specify ……

20. Over the next six months if you find a spot or mole that you are worried about what will you do?

You may tick one or more options

☐ 1 Show it to a partner, relative or friend

Would you do this:

☐ 1 Immediately

☐ 2 Within a few days

☐ 3 Within a week

☐ 4 Within a month

☐ 5 Other, please specify

☐ 2 Make an appointment with a doctor

Would you do this:

☐ 1 Immediately

☐ 2 Within a few days

☐ 3 Within a week

☐ 4 Within a month

☐ 5 Other, please specify

☐ 3 Contact the specialist nurse

Would you do this:

☐ 1 Immediately

☐ 2 Within a few days

☐ 3 Within a week

☐ 4 Within a month

☐ 5 Other, please specify

☐ 4 Watch it until the next prompt from the ASICA tablet arrives

☐ 5 Watch and wait

☐ 6 Other, please specify .....

Health Professional Skin Examination

21. Has a doctor or nurse ever deliberately checked any part of your skin for early signs of skin cancer since you received the ASICA electronic tablet?

☐ 1 Yes → Go to Q22

☐ 2 No → Go to Q26

☐ 3 Don't know → Go to Q26

22. In the past 12 months, has a doctor or nurse deliberately checked any part of your skin for early signs of skin cancer?

☐ 1 Yes → Go to Q23

☐ 2 No → Go to Q26

☐ 3 Don't know → Go to Q26

23. In the past 12 months has a doctor or nurse deliberately checked the skin on your whole body? Usually this would involve taking your clothes off at least down to your underwear.

☐ 1 Yes

☐ 2 No

☐ 3 Don't know

24. During your last skin check did the doctor suggest you check your own skin for early signs of skin cancer?

☐ 1 Yes ☐ 2 No

25. Did the doctor show you how to check your own skin for early signs of skin cancer?

☐ 1 Yes ☐ 2 No

Attitudes and Beliefs

For this section of the questionnaire we would like to find out what you think about checking your skin.

26. For each of the following statements please indicate whether you strongly disagree, disagree, agree, strongly agree, or are unsure with each statement. ***Please select only one option for each question.***

	Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree
a. It is important to check my skin for skin cancer even if I have no symptoms	☐1	☐2	☐3	☐4	☐5
b. Checking my skin would make me anxious.	☐1	☐2	☐3	☐4	☐5
c. Checking my skin regularly is a priority for me.	☐1	☐2	☐3	☐4	☐5
d. I could find something suspicious on my skin if it was there.	☐1	☐2	☐3	☐4	☐5
e. If I saw something suspicious on my skin, I'd go to the doctor straight away.	☐1	☐2	☐3	☐4	☐5
f. I am confident in a doctor's ability to diagnose skin cancer.	☐1	☐2	☐3	☐4	☐5
g. I have made plans about when to examine my own skin.	☐1	☐2	☐3	☐4	☐5
h. I have made plans about where I will be when I examine my skin.	☐1	☐2	☐3	☐4	☐5
i. If I don't manage to examine my skin as planned I will find another opportunity.	☐1	☐2	☐3	☐4	☐5

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How You Feel

Please read each item and place a tick in the box beside the reply which comes closest to how you have been feeling **in the past week**. Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought-out response. **Please tick only one box in each section**

1. I feel tense or 'wound up':
- Most of the time ☐
- A lot of the time ☐
- Time to time, Occasionally ☐
- Not at all ☐

2. I feel as if I am slowed down:
- Nearly all the time ☐
- Very often ☐
- Sometimes ☐
- Not at all ☐

3. I still enjoy the things I used to enjoy:
- Definitely as much ☐
- Not quite as much ☐
- Only a little ☐
- Hardly at all ☐

4. I get a sort of frightened feeling like 'butterflies' in the stomach:
- Not at all ☐
- Occasionally ☐
- Quite often ☐
- Very often ☐

5. I get a sort of frightened feeling as if something awful is about to happen:
- Very definitely and quite badly ☐
- Yes, but not too badly ☐
- A little, but it doesn't worry me ☐
- Not at all ☐

6. I have lost interest in my appearance:
- Definitely ☐
- I don't take so much care as I should ☐
- I may not take quite as much care ☐
- I take just as much care as ever ☐

7. I can laugh and see the funny side of things:
- As much as I always could ☐
- Not quite so much now ☐
- Definitely not so much now ☐
- Not at all ☐

8. I feel restless as if I have to be on the move:
- Very much indeed ☐
- Quite a lot ☐
- Not very much ☐
- Not at all ☐

9. Worrying thoughts go through my mind:
- A great deal of the time ☐
- A lot of the time ☐
- From time to time but not too often ☐
- Only occasionally ☐

10. I look forward with enjoyment to things:
- As much as ever I did ☐
- Rather less than I used to ☐
- Definitely less than I used to ☐
- Hardly at all ☐

11. I feel cheerful:
- Not at all ☐
- Not often ☐
- Sometimes ☐
- Most of the time ☐

12. I get sudden feelings of panic:
- Very often indeed ☐
- Quite often ☐
- Not very often ☐
- Not at all ☐

13. I can sit at ease and feel relaxed:
- Definitely ☐
- Usually ☐
- Not often ☐
- Not at all ☐

14. I can enjoy a good book or radio or TV programme:
- Often ☐
- Sometimes ☐
- Not often ☐
- Very seldom ☐

Other Health Conditions

This section will cover questions about diseases and health conditions that you may already have or have had in the past.

27. Has a doctor ever told you that you have or have had any of the following conditions?

PLEASE TICK ALL THAT APPLY AND GIVE YOUR AGE AT FIRST DIAGNOSIS

	No [1]	Yes [2]	Age at first diagnosis	Don't know [3]
1. Heart Conditions (Heart Attack, Coronary, Myocardial Infarction, Angina Pectoris)				
2. High Blood Pressure/Hypertension				
3. High Cholesterol/Lipid Problems				
4. Stroke				
5. Diabetes/High Blood Sugar				
6. Lung Conditions (Asthma/Chronic Bronchitis/Emphysema Chronic Obstructive Lung Disease/COPD)				
7. Stomach or Duodenal Ulcer				
8. Chronic Headaches/Migraine				
9. Musculo-skeletal Disorders (Osteoporosis, Back Problems)				
10. Arthritis (Osteoarthritis/Rheumatoid Arthritis)/other joint complaints				

	No [1]	Yes [2]	Age at first diagnosis	Don't know [3]
11. Cancer/Leukaemia (excluding skin cancer)				
12. Problems with eye sight which could make it difficult to examine my own skin				
13. Mental health problems (Anxiety, Depression, Post-traumatic Stress Disorder)				
14. Problems with mobility which could make it difficult to examine my own skin				
15. Any other prolonged or serious illness? If yes, please specify below. _____				

Please list any medication, including over the counter medicines, that you are taking in the space below.

Personal Background

And finally …… some questions about yourself.

28. Are you

- ☐ 1 20-30
- ☐ 2 31-40
- ☐ 3 41-50
- ☐ 4 51-60
- ☐ 5 61-70
- ☐ 6 71-80
- ☐ 7 81-90
- ☐ 8 91 or older

29. Do you live?

- ☐ On your own
- ☐ With a partner/spouse
- ☐ With other family *(Please say who)* ☐
- ☐ Other *(Please say who)* ☐

30. How would you <u>best</u> describe your current work situation?

- ☐ 1 Employed full-time (include self-employed/business/farming)
- ☐ 2 Employed part-time or casual (include self-employed/business/farming)
- ☐ 3 Full-time home duties/home-carer
- ☐ 4 Student
- ☐ 5 Unemployed or looking for work
- ☐ 6 Retired
- ☐ 7 Permanently ill/unable to work
- ☐ 8 Other (please specify) ……

31. Is your main job or activity now…?

☐ 1 Mainly indoors

☐ 2 Mainly outdoors

☐ 3 About equal amounts indoors and outdoors

32. What is your present marital status?

☐ 1 Married/living together

☐ 2 Divorced/separated

☐ 3 Widowed

☐ 4 Single/never married

☐ 5 Other (please specify) ……

33. Approximately what is the distance from your home to your GP

☐ Minutes by car

☐ Miles

34. Do you: (Please tick one box only)

☐ Own your home

☐ Rent your home

☐ Other (Please state……..)

Thank you for helping us with this important research.

If you have any comments about any of the questions that we have asked, please add them here.

Thank you for completing this survey. Please return it using the reply-paid envelope provided (NO STAMP IS NEEDED)

Digitally supported total skin self-examination at home for people treated for cutaneous melanoma: developing and simulating experience of the ASICA intervention. Murchie et al

APPENDIX 2: Experience lab outcomes

BENEFITS – "WHAT DO I GET FROM THIS?": Developing motivation to engage with ASICA and TSSE

Patient volunteers perceived the following advantages of the ASICA intervention: reduced travel and time; having your own skin map (an aide memoire and evidence if needed); speed and simplicity of the process; rapid reassurance when concerned; raised awareness of caring for my skin and empowerment; feels like the medical staff care for me; secure and I can trust the NHS with my information.

COMPONENTS – "NUTS AND BOLTS TO MAKE IT WORK": Action plans to enable TSSE and maintenance of use of ASICA

THE CUE TO ACTION

The email reminder should be sent at the right time – no point sending it on a Friday evening when the patient will be unable to get a response until the following Monday. It seems sensible, therefore, that these would be sent at the beginning of a week. It was also viewed as sensible to send this to another device/using another mechanism to get round the risk that the tablet may be stored in a drawer between skin-checks.

THE INSTRUCTIONAL VIDEO

The video to be embedded within ASICA had the following aims:

- To introduce self-monitoring
- To incentivise a personal skin check
- To provide persuasion from a credible source
- To provide behavioural instruction
- To demonstrate the required behaviour
- To provide information about health consequences

Comments on the existing video were generally negative. It was described as too long and repetitive and in need of "spicing up." However at least two of the patient volunteers warned that it needed to continue to be comprehensive.

Particular issues for improvement of the video were:

Provide incentive: There was nothing on the video that suggested participants might expect a better outcome by doing a personal skin check. This incentive does not have to be much – it could just be 'By doing this you will get early attention to any problems which the clinic can then deal with' You don't have to say you will save their lives.

Provide Information: Tell us why we are doing this and what we are looking for at each stage. Give us some information about moles (e.g. where are they most likely to be found). Tell us specifically what the things we are worried about look/feel like. Tell us how long the examination will take.

Have an inspiring voice over: The lady on the video was felt to be monotonous.

Make the background less gloomy: The dark background made the video seem oppressive.

Make the video less repetitive: Basic techniques should be explained once, i.e. examining skin and feeling for lumps.

Tailor the video: Give a video of a man for men and a woman for women.

Idealised body: Participants generally felt that a model with an "ideal" body was preferable to more realistic appearance.

Presence of moles: The model should have some moles. We should see them examining the moles as we would want them to do in the behaviour. We should also see how the patient would record this information within the intervention. This should be re-emphasis in each section of the video (i.e. after "The scalp" "The head" "The back".)

Use "point of view" perspective: To differentiate parts of the video where you are looking versus feeling. The video should make it clear that "Looking" and "Feeling" are two very different behaviours. This means that the video should emphasise both behaviours. The video should clearly distinguish between "looking" and "feeling." The video should show what people might see when they "look." Similarly, they should be shown how to "feel". This needs to be tailored to parts of the body – i.e. what are the hands doing when the patient is feeling the back of their legs. Video needs to introduce elements of how to feel for lumps, emphasising those that are practically shown at the training day.

Helpers: The EP day made it clear that people are going to be challenged to examine their back and their scalp. It might be good for the video to introduce the idea of "helpers" and a range of whom these might be – e.g. friends, spouse, carers, parents, children, GPs. It would then be good practice to ask the patients to identify an appropriate helper, a person whom they would most like to involve at recruitment. Perhaps a solution needs to be found for those that can't identify a helper.

Make the video interactive: Split into sections (e.g. head and neck, arms, legs) so that participants can tailor how they do the examination. It will also be important to structure it this way to facilitate a sequence, so that people can tick sections as they go along. The video, therefore, needs to be structured with reference to the check list which will be on the tablet. We should consider having a separate checklist for each part of the body. There is a need, however, to guard against making the system too complicated.

Consequently a new animated video was professionally produced for incorporation onto the tablet.

THE SKIN MAP

What are the technology options for this? Does it need to be broken down or could it be presented as a whole body or video map. It is likely that patients will need to visit Aberdeen for this to be done. Some of Susan's findings from the interviews suggest that this aspect of the project will need to be handled sensitively, one patient reported that having the skin map formed was a humiliating experience. Patients suggested that they wanted to be able to mark any concerns directly on their skin maps. They wanted to able to zoom in to see the detail of the skin map and also to be able to move the photo around, i.e. to see the next body part using the touch screen.

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In consequence arrangements were made at Medical Illustration at University of Aberdeen for each patient to have digital skin map images taken. These were subsequently incorporated onto individual Google Tablets for individual patients.

THE REPORT FORM

The report back form should include options for labelling and a free-text box to explain the outcome, e.g. new mole, new spot, lump, no concerns etc. Patients preferred not to have the option to mark the report urgent – felt that this is something for specialists to decide. Previous report backs should be stored within the app for future reference

PROCESSES – "FLOWS OF INFORMATION"

LANGUAGE

Language used throughout should be chosen with care. In particular, when asking people to perform tasks language should be simple. For example, the term "Personal Skin Check" was perceived as more meaningful, understanding and less daunting to an individual than "Total Skin Self-Examination." Language needs to communicate what they are being asked to do; why they are being asked to do it; how to do it; what might happen when they do it; what the corresponding consequences and further actions of outcomes is.

TRAINING THE USER

Training eventual participants in the pilot exercise will be key.

The issue of engaging participants with the technology is important. The consensus from the plenary was that patients would be more likely to embrace the use of the technology if it was presented in conjunction with the benefits of using technology and the incentives listed about. (e.g. less travel, more control etc). It will also make sense to introduce the technology used as "just something used in healthcare." Patients can manage many much more complex activities and equipment than are being proposed here, for example nebulisers, home oxygen and glucose monitoring in diabetes.

The training must, however, show people how to do the intervention. As one specialist has pointed out one of the main purposes of follow-up appointments is to detect nodal disease. For this reason the individual participants should be shown how to examine their appropriate lymph node basins (neck, groins or axilla. These are practical skills that need to be demonstrated and can be reiterated on the video

However, it will be important not to make the assumption that people will manage to use the tablet/technology. Appropriate training will, and should be delivered. It will also be important to recognise that younger people may be more easily able to engage with the technology. Nevertheless there is a danger of making assumptions according to age stereotypes. We should aim for a standardised non-ageist way of introducing the technology and training people in the system. We should guard against training which is patronising and offensive to older people and too sketchy for younger patients leaving them less well informed.

REPORTING TO THE SPECIALIST

Several functions of the intervention are encapsulated within this step. In most cases patients will be feeding back negative findings. This will convey a sense of reassurance to them and

will, in effect, be the reward for performing the behaviour. In other circumstances a new lesion will be found. In this case, a decision on what is to happen will be available within 48 hours, much quicker than under existing systems. It is likely, therefore that both outcomes will reinforce the behaviour.

There were few concerns from patients about communicating information (including body images remotely). They would assume that security was in place. Technology experts offered "scrambling", "encryption and "cropping images" as further means to ensure security.

FEEDBACK FROM THE SPECIALIST

When the report (no concern) or issue arising is returned participants would want to receive a "report received" receipt. They felt this should be tailored to reflect how long it would take to get a response. It should also provide a phone number which could be contacted if the patient was concerned meantime.

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