CONSORT-EHEALTH Checklist V1.6.2 Report	Manuscript Number	37539
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by		
Peter Murchie		
The Achieving Self-directed Integrated Cancer Aftercare Intervention for Detection of Recurrent and Second Primary Melanoma in Survivors of Melanoma: Pilot Randomized Controlled Tria		
TITLE		
1a-i) Identify the mode of delivery in the title		
The Achieving Self-Directed Integrated Cancer Aftercare (ASICA) intervention for detection of recurrent and second primary melanoma in melanoma survivors: A randomised controlled pilot trial		
1a-ii) Non-web-based components or important co-interventions in title		
The Achieving Self-Directed Integrated Cancer Aftercare (ASICA) intervention for detection of recurrent and second primary melanoma in melanoma survivors: A randomised controlled pilot trial		
1a-iii) Primary condition or target group in the title		
The Achieving Self-Directed Integrated Cancer Aftercare (ASICA) intervention for detection of recurrent and second primary melanoma in melanoma survivors: A randomised controlled pilot trial		
ABSTRACT		
1b-i) Key features/functionalities/components of the intervention and comparator in the METHODS section of the ABSTRACT		
ASICA (Achieving Self-directed Integrated Cancer Aftercare) a tablet-based digital intervention to prompt and support TSSE in melanoma survivors, or to usual care		
1b-ii) Level of human involvement in the METHODS section of the ABSTRACT		
Adults (aged ≥18) diagnosed with a first 0-IIC primary cutaneous melanoma were randomised to receive ASICA (Achieving Self-directed Integrated Cancer Aftercare) a tablet-based digital intervention to prompt and support TSSE in melanoma survivors, or to usual care.		
1b-iii) Open vs. closed, web-based (self-assessment) vs. face-to-face assessments in the METHODS section of the ABSTRACT		
Adults (aged ≥18) diagnosed with a first 0-IIC primary cutaneous melanoma were randomised to receive ASICA (Achieving Self-directed Integrated Cancer Aftercare) a tablet-based digital intervention to prompt and support TSSE in melanoma survivors, or to usual care.		
1b-iv) RESULTS section in abstract must contain use data		
Adults (aged ≥18) diagnosed with a first 0-IIC primary cutaneous melanoma were randomised to receive ASICA (Achieving Self-directed Integrated Cancer Aftercare) a tablet-based digital intervention to prompt and support TSSE in melanoma survivors, or to usual care.		
1b-v) CONCLUSIONS/DISCUSSION in abstract for negative trials		
Using ASICA for 12 months does not increase melanoma worry, can reduce anxiety and depression and may improve quality of life. ASICA has the potential to improve well-being and vigilance of melanoma survivors and enable the benefits of regular TSSE		
INTRODUCTION		
2a-i) Problem and the type of system/solution		
The aim of this pilot study was to evaluate the ASICA self-directed digital intervention in a patient-focused randomized controlled trial among those treated for a first stage 0-2C primary cutaneous melanoma within the preceding 60 months. The primary objective of the pilot study was to determine the impact of using ASICA on patient's melanoma worry, anxiety and depression and quality of life. The secondary objective was to provide information on the feasibility of processes for a full-scale national trial of the ASICA intervention		
2a-ii) Scientific background, rationale: What is known about the (type of) system		
The aim of this pilot study was to evaluate the ASICA self-directed digital intervention in a patient-focused randomized controlled trial among those treated for a first stage 0-2C primary cutaneous melanoma within the preceding 60 months. The primary objective of the pilot study was to determine the impact of using ASICA on patient's melanoma worry, anxiety and depression and quality of life. The secondary objective was to provide information on the feasibility of processes for a full-scale national trial of the ASICA intervention		
Does your paper address CONSORT subitem 2b?		
The aim of this pilot study was to evaluate the ASICA self-directed digital intervention in a patient-focused randomized controlled trial among those treated for a first stage 0-2C primary cutaneous melanoma within the preceding 60 months. The primary objective of the pilot study was to determine the impact of using ASICA on patient's melanoma worry, anxiety and depression and quality of life. The secondary objective was to provide information on the feasibility of processes for a full-scale national trial of the ASICA intervention		
METHODS		
3a) CONSORT: Description of trial design (such as parallel, factorial) including allocation ratio		
ASICA was a two-arm, open, two-centre randomised controlled pilot trial (RCT) comparing the ASICA digital intervention with a control group receiving usual follow-up only (Figure 1). The study sites were Aberdeen Royal Infirmary and Addenbrooke's Hospital, Cambridge. Adults (≥18 years) treated within the preceding 60 months for a previous stage 0-IIC primary cutaneous melanoma were sent information about the study, a consent form and baseline questionnaire by post. Individuals diagnosed with stage 3 and 4 melanoma, recurrent melanoma within the last 60 months or unable to consent and/or complete questionnaires were excluded. Those interested in participating in the study were contacted by the recruiting site to discuss further. Participants were randomised after informed written consent had been obtained.		
3b) CONSORT: Important changes to methods after trial commencement (such as eligibility criteria), with reasons		
This is not applicable as there were no changes		
3b-i) Bug fixes, Downtimes, Content Changes		
This is not applicable as there were no bug fixes, downtime or content changes		
4a) CONSORT: Eligibility criteria for participants		
Eligibility criteria are included in the manuscript		
4a-i) Computer / Internet literacy		
This was not an appropriate eligbility criteria for this study		
4a-ii) Open vs. closed, web-based vs. face-to-face assessments:		
The study sites were Aberdeen Royal Infirmary and Addenbrooke's Hospital, Cambridge. Adults (≥18 years) treated within the preceding 60 months for a previous stage 0-IIC primary cutaneous melanoma were sent information about the study, a consent form and baseline questionnaire by post.		
4a-iii) Information giving during recruitment		
The study sites were Aberdeen Royal Infirmary and Addenbrooke's Hospital, Cambridge. Adults (≥18 years) treated within the preceding 60 months for a previous stage 0-IIC primary cutaneous melanoma were sent information about the study, a consent form and baseline questionnaire by post.		
4b) CONSORT: Settings and locations where the data were collected		
Baseline data were collected from secondary care records by a research nurse at each site before randomisation. The co-primary outcomes were Melanoma Worry Scale (MWS), anxiety and depression (HADS) and quality of life (EQ-5D-5L) [19]. Secondary outcomes were adherence to TSSE recommendations, self-efficacy and future intention and planning to perform TSSE[22]. Primary and secondary outcomes were collected by postal questionnaires at baseline, 3, 6- and 12-months after randomisation. Tertiary outcomes were new primary and recurrent melanomas and patterns of skin-related NHS resource use. These were collected 12 months after randomisation from secondary care records by research nurses blind to allocation.		
4b-i) Report if outcomes were (self-)assessed through online questionnaires		
Baseline data were collected from secondary care records by a research nurse at each site before randomisation. The co-primary outcomes were Melanoma Worry Scale (MWS), anxiety and depression (HADS) and quality of life (EQ-5D-5L) [19]. Secondary outcomes were adherence to TSSE recommendations, self-efficacy and future intention and planning to perform TSSE[22]. Primary and secondary outcomes were collected by postal questionnaires at baseline, 3, 6- and 12-months after randomisation. Tertiary outcomes were new primary and recurrent melanomas and patterns of skin-related NHS resource use. These were collected 12 months after randomisation from secondary care records by research nurses blind to allocation.		
4b-ii) Report how institutional affiliations are displayed		
This project received full approval from the North of Scotland Research Ethics Committee on 28th April 2017 ((17/NS/0040). Written informed consent was obtained from all study participants. The trial was conducted according to the principles of good clinical practice provided by Research Governance Guidelines. Consent for publication did not apply		
5) CONSORT: Describe the interventions for each group with sufficient details to allow replication, including how and when they were actually administered		
5-i) Mention names, credential, affiliations of the developers, sponsors, and owners		
The necessary information is provided in the manuscript		
5-ii) Describe the history/development process		
This has been described in an earlier publication		
5-iii) Revisions and updating		
These items are beyond the scope if the trial report		
5-iv) Quality assurance methods		

Not applicable to the current study		
5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used		
These items are not relevant to the current trial report and available elsewhere		
5-vi) Digital preservation		
The intervention has been archieved		
5-vii) Access		
Briefly, intervention group participants attended a 30-minute training session at which they were issued with a seven-inch Samsung Galaxy tablet and given instruction on the intervention and how the tablet computer-base application (app) should be used to support them to conduct a thorough full-body TSSE in response to a monthly SMS text reminder sent from the trial team. The nurse demonstrated the function of the app and answered any questions about TSSE or the intervention. The app included information about the importance of monthly TSSE, instructional videos demonstrating how to perform a TSSE and take good photographs of skin lesions, a digital map of the patient's own skin, a structured checkbox list of body parts to check, prompts for the patient to plan their next TSSE and the capability to take photographs of suspicious skin lesions and send them to a dermatology nurse practitioner for review along with a text-based report of the TSSE outcomes including a description of any concerns. All participants who submitted text-based reports of any skin concerns were followed-up by the dermatology nurse practitioner.The monthly prompt was sent on a single occasion and no reminders were sent to individuals who did not complete the TSSE that month, but they would continue to be reminded on each subsequent month. The control group also completed the baseline questionnaire. All participants (intervention and control) continued to attend their usual structured melanoma follow-up as determined by local guidelines		
5-viii) Mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework		
Briefly, intervention group participants attended a 30-minute training session at which they were issued with a seven-inch Samsung Galaxy tablet and given instruction on the intervention and how the tablet computer-base application (app) should be used to support them to conduct a thorough full-body TSSE in response to a monthly SMS text reminder sent from the trial team. The nurse demonstrated the function of the app and answered any questions about TSSE or the intervention. The app included information about the importance of monthly TSSE, instructional videos demonstrating how to perform a TSSE and take good photographs of skin lesions, a digital map of the patient's own skin, a structured checkbox list of body parts to check, prompts for the patient to plan their next TSSE and the capability to take photographs of suspicious skin lesions and send them to a dermatology nurse practitioner for review along with a text-based report of the TSSE outcomes including a description of any concerns. All participants who submitted text-based reports of any skin concerns were followed-up by the dermatology nurse practitioner.The monthly prompt was sent on a single occasion and no reminders were sent to individuals who did not complete the TSSE that month, but they would continue to be reminded on each subsequent month. The control group also completed the baseline questionnaire. All participants (intervention and control) continued to attend their usual structured melanoma follow-up as determined by local guidelines		
5-ix) Describe use parameters		
Briefly, intervention group participants attended a 30-minute training session at which they were issued with a seven-inch Samsung Galaxy tablet and given instruction on the intervention and how the tablet computer-base application (app) should be used to support them to conduct a thorough full-body TSSE in response to a monthly SMS text reminder sent from the trial team. The nurse demonstrated the function of the app and answered any questions about TSSE or the intervention. The app included information about the importance of monthly TSSE, instructional videos demonstrating how to perform a TSSE and take good photographs of skin lesions, a digital map of the patient's own skin, a structured checkbox list of body parts to check, prompts for the patient to plan their next TSSE and the capability to take photographs of suspicious skin lesions and send them to a dermatology nurse practitioner for review along with a text-based report of the TSSE outcomes including a description of any concerns. All participants who submitted text-based reports of any skin concerns were followed-up by the dermatology nurse practitioner.The monthly prompt was sent on a single occasion and no reminders were sent to individuals who did not complete the TSSE that month, but they would continue to be reminded on each subsequent month. The control group also completed the baseline questionnaire. All participants (intervention and control) continued to attend their usual structured melanoma follow-up as determined by local guidelines		
5-x) Clarify the level of human involvement		
Briefly, intervention group participants attended a 30-minute training session at which they were issued with a seven-inch Samsung Galaxy tablet and given instruction on the intervention and how the tablet computer-base application (app) should be used to support them to conduct a thorough full-body TSSE in response to a monthly SMS text reminder sent from the trial team. The nurse demonstrated the function of the app and answered any questions about TSSE or the intervention. The app included information about the importance of monthly TSSE, instructional videos demonstrating how to perform a TSSE and take good photographs of skin lesions, a digital map of the patient's own skin, a structured checkbox list of body parts to check, prompts for the patient to plan their next TSSE and the capability to take photographs of suspicious skin lesions and send them to a dermatology nurse practitioner for review along with a text-based report of the TSSE outcomes including a description of any concerns. All participants who submitted text-based reports of any skin concerns were followed-up by the dermatology nurse practitioner.The monthly prompt was sent on a single occasion and no reminders were sent to individuals who did not complete the TSSE that month, but they would continue to be reminded on each subsequent month. The control group also completed the baseline questionnaire. All participants (intervention and control) continued to attend their usual structured melanoma follow-up as determined by local guidelines		
5-xi) Report any prompts/reminders used		
Briefly, intervention group participants attended a 30-minute training session at which they were issued with a seven-inch Samsung Galaxy tablet and given instruction on the intervention and how the tablet computer-base application (app) should be used to support them to conduct a thorough full-body TSSE in response to a monthly SMS text reminder sent from the trial team. The nurse demonstrated the function of the app and answered any questions about TSSE or the intervention. The app included information about the importance of monthly TSSE, instructional videos demonstrating how to perform a TSSE and take good photographs of skin lesions, a digital map of the patient's own skin, a structured checkbox list of body parts to check, prompts for the patient to plan their next TSSE and the capability to take photographs of suspicious skin lesions and send them to a dermatology nurse practitioner for review along with a text-based report of the TSSE outcomes including a description of any concerns. All participants who submitted text-based reports of any skin concerns were followed-up by the dermatology nurse practitioner.The monthly prompt was sent on a single occasion and no reminders were sent to individuals who did not complete the TSSE that month, but they would continue to be reminded on each subsequent month. The control group also completed the baseline questionnaire. All participants (intervention and control) continued to attend their usual structured melanoma follow-up as determined by local guidelines		
5-xii) Describe any co-interventions (incl. training/support)		
Briefly, intervention group participants attended a 30-minute training session at which they were issued with a seven-inch Samsung Galaxy tablet and given instruction on the intervention and how the tablet computer-base application (app) should be used to support them to conduct a thorough full-body TSSE in response to a monthly SMS text reminder sent from the trial team. The nurse demonstrated the function of the app and answered any questions about TSSE or the intervention. The app included information about the importance of monthly TSSE, instructional videos demonstrating how to perform a TSSE and take good photographs of skin lesions, a digital map of the patient's own skin, a structured checkbox list of body parts to check, prompts for the patient to plan their next TSSE and the capability to take photographs of suspicious skin lesions and send them to a dermatology nurse practitioner for review along with a text-based report of the TSSE outcomes including a description of any concerns. All participants who submitted text-based reports of any skin concerns were followed-up by the dermatology nurse practitioner.The monthly prompt was sent on a single occasion and no reminders were sent to individuals who did not complete the TSSE that month, but they would continue to be reminded on each subsequent month. The control group also completed the baseline questionnaire. All participants (intervention and control) continued to attend their usual structured melanoma follow-up as determined by local guidelines		
6a) CONSORT: Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed		
Baseline data were collected from secondary care records by a research nurse at each site before randomisation. The co-primary outcomes were Melanoma Worry Scale (MWS), anxiety and depression (HADS) and quality of life (EQ-5D-5L) [19]. Secondary outcomes were adherence to TSSE recommendations, self-efficacy and future intention and planning to perform TSSE[22]. Primary and secondary outcomes were collected by postal questionnaires at baseline, 3, 6- and 12-months after randomisation. Tertiary outcomes were new primary and recurrent melanomas and patterns of skin-related NHS resource use. These were collected 12 months after randomisation from secondary care records by research nurses blind to allocation.		
6a-i) Online questionnaires: describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed		
Baseline data were collected from secondary care records by a research nurse at each site before randomisation. The co-primary outcomes were Melanoma Worry Scale (MWS), anxiety and depression (HADS) and quality of life (EQ-5D-5L) [19]. Secondary outcomes were adherence to TSSE recommendations, self-efficacy and future intention and planning to perform TSSE[22]. Primary and secondary outcomes were collected by postal questionnaires at baseline, 3, 6- and 12-months after randomisation. Tertiary outcomes were new primary and recurrent melanomas and patterns of skin-related NHS resource use. These were collected 12 months after randomisation from secondary care records by research nurses blind to allocation.		
6a-ii) Describe whether and how "use" (including intensity of use/dosage) was defined/measured/monitored		
These are beyond the scope of the current paper and reported in a separate publication		
6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained		
A separate qualitative manuscript has been submitted		
6b) CONSORT: Any changes to trial outcomes after the trial commenced, with reasons		
Baseline data were collected from secondary care records by a research nurse at each site before randomisation. The co-primary outcomes were Melanoma Worry Scale (MWS), anxiety and depression (HADS) and quality of life (EQ-5D-5L) [19]. Secondary outcomes were adherence to TSSE recommendations, self-efficacy and future intention and planning to perform TSSE[22]. Primary and secondary outcomes were collected by postal questionnaires at baseline, 3, 6- and 12-months after randomisation. Tertiary outcomes were new primary and recurrent melanomas and patterns of skin-related NHS resource use. These were collected 12 months after randomisation from secondary care records by research nurses blind to allocation.		
7a) CONSORT: How sample size was determined		
7a-i) Describe whether and how expected attrition was taken into account when calculating the sample size		
7b) CONSORT: When applicable, explanation of any interim analyses and stopping guidelines		

Baseline data were collected from secondary care records by a research nurse at each site before randomisation. The co-primary outcomes were Melanoma Worry Scale (MWS), anxiety and depression (HADS) and quality of life (EQ-5D-5L) [19]. Secondary outcomes were adherence to TSSE recommendations, self-efficacy and future intention and planning to perform TSSE[22]. Primary and secondary outcomes were collected by postal questionnaires at baseline, 3, 6- and 12-months after randomisation. Tertiary outcomes were new primary and recurrent melanomas and patterns of skin-related NHS resource use. These were collected 12 months after randomisation from secondary care records by research nurses blind to allocation.		
8a) CONSORT: Method used to generate the random allocation sequence		
Participants were randomised 1:1 to intervention or control using a remote automated computer-allocated application hosted at the Centre for Healthcare Randomised Trials (CHaRT) in Aberdeen, UK. An algorithm minimised imbalance in sex and centre between groups[21]. Due to the nature of the intervention, both participants and researchers were not masked to randomised allocation.		
8b) CONSORT: Type of randomisation; details of any restriction (such as blocking and block size)		
Participants were randomised 1:1 to intervention or control using a remote automated computer-allocated application hosted at the Centre for Healthcare Randomised Trials (CHaRT) in Aberdeen, UK. An algorithm minimised imbalance in sex and centre between groups[21]. Due to the nature of the intervention, both participants and researchers were not masked to randomised allocation.		
9) CONSORT: Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned		
Participants were randomised 1:1 to intervention or control using a remote automated computer-allocated application hosted at the Centre for Healthcare Randomised Trials (CHaRT) in Aberdeen, UK. An algorithm minimised imbalance in sex and centre between groups[21]. Due to the nature of the intervention, both participants and researchers were not masked to randomised allocation.		
10) CONSORT: Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions		
Participants were randomised 1:1 to intervention or control using a remote automated computer-allocated application hosted at the Centre for Healthcare Randomised Trials (CHaRT) in Aberdeen, UK. An algorithm minimised imbalance in sex and centre between groups[21]. Due to the nature of the intervention, both participants and researchers were not masked to randomised allocation.		
11a) CONSORT: Blinding - If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		
11a-i) Specify who was blinded, and who wasn't		
Blinding was not possible in this study		
11a-ii) Discuss e.g., whether participants knew which intervention was the "intervention of interest" and which one was the "comparator"		
participant knew if they were in the intervention or control group		
11b) CONSORT: If relevant, description of the similarity of interventions		
There was only one intervention trialled		
12a) CONSORT: Statistical methods used to compare groups for primary and secondary outcomes		
A statistical analysis section is provided in the manuscript		
12a-i) Imputation techniques to deal with attrition / missing values		
These were not employed in the current study		
12b) CONSORT: Methods for additional analyses, such as subgroup analyses and adjusted analyses		
There were no subgroup analyses conducted		
RESULTS		
13a) CONSORT: For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome		
This information is within the results section and tables		
13b) CONSORT: For each group, losses and exclusions after randomisation, together with reasons		
A study flow diagram is included in the manuscript		
13b-i) Attrition diagram		
A study flow diagram is included in the manuscript		
14a) CONSORT: Dates defining the periods of recruitment and follow-up		
Between 24 January 2018 and 8 March 2019, 240 participants were randomised (121 to the ASICA intervention,119 to usual care).		
14a-i) Indicate if critical "secular events" fell into the study period		
This is not relevant to the current study		
14b) CONSORT: Why the trial ended or was stopped (early)		
This is not relevant to the current study		
15) CONSORT: A table showing baseline demographic and clinical characteristics for each group		
This is included in the manuscript		
15-i) Report demographics associated with digital divide issues		
Demographics are reported in the paper		
16a) CONSORT: For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups		
16-i) Report multiple "denominators" and provide definitions		
This information is reported in the paper		
16-ii) Primary analysis should be intent-to-treat		
The analysis was by the intention-to-treat principle		
17a) CONSORT: For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)		
This information is reported in the results section and the tables		
17a-i) Presentation of process outcomes such as metrics of use and intensity of use		
This information has been presented in another publication		
17b) CONSORT: For binary outcomes, presentation of both absolute and relative effect sizes is recommended		
This information is reported in the paper		
18) CONSORT: Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		
All relevant analyses are reported in the paper		
18-i) Subgroup analysis of comparing only users		
This is not relevant to the current study		
19) CONSORT: All important harms or unintended effects in each group		
This information is reported in the manuscript		
19-i) Include privacy breaches, technical problems		
This is not relevant to the current manuscript		
19-ii) Include qualitative feedback from participants or observations from staff/researchers		
Qualitative feedback is being reported in another related publication		
DISCUSSION		
20) CONSORT: Trial limitations, addressing sources of potential bias, imprecision, multiplicity of analyses		
20-i) Typical limitations in ehealth trials		
We provide a structured discussion in the paper		
21) CONSORT: Generalisability (external validity, applicability) of the trial findings		
21-i) Generalizability to other populations		
We provide a structured discussion in the paper		
21-ii) Discuss if there were elements in the RCT that would be different in a routine application setting		
We provide a structured discussion in the paper		
22) CONSORT: Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		
22-i) Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use)		
We provide a structured discussion in the paper		
22-ii) Highlight unanswered new questions, suggest future research		
We provide a structured discussion in the paper		
Other information		
23) CONSORT: Registration number and name of trial registry		
This information is provided		
24) CONSORT: Where the full trial protocol can be accessed, if available		
The full protocol is reference in the paper		
25) CONSORT: Sources of funding and other support (such as supply of drugs), role of funders		

This information is provided in the manuscript		
X26-i) Comment on ethics committee approval		
This project received full approval from the North of Scotland Research Ethics Committee on 28th April 2017 ((17/NS/0040). Written informed consent was obtained from all study participants. The trial was conducted according to the principles of good clinical practice provided by Research Governance Guidelines. Consent for publication did not apply		
x26-ii) Outline informed consent procedures		
Those interested in participating in the study were contacted by the recruiting site to discuss further. Participants were randomised after informed written consent had been obtained.		
X26-iii) Safety and security procedures		
These are not specifically discussed in the current trial report		
X27-i) State the relation of the study team towards the system being evaluated		
This information is provided in the manuscript		