# Barriers and facilitators of adherence to the use of ASICA, a digital app designed to support people previously treated for melanoma: concise report of a qualitative study

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#### Abstract

We developed the Achieving Self-directed Integrated Cancer Aftercare (ASICA) in melanoma app to support monthly total-skin self-examinations (TSSE) by people previously treated for melanoma. A randomized 12-month trial demonstrated ASICA supported optimal monthly TSSE adherence in a third of participants (ClinicalTrials.gov NCT03328247). However, a further third of participants adhered well initially but subsequently dropped off, and a final third did not adhere at all. This follow-up qualitative study investigated trial participants' perceptions of barriers and facilitators to TSSE adherence using the app. Three former trial participants participated in a single focus group and 11 participated in new semistructured telephone interviews. These were analysed thematically alongside secondary analysis of 13 qualitative interviews conducted during the trial. All transcripts were recorded, transcribed and analysed thematically. Five themes encompassing barriers and facilitators to ASICA adherence emerged. These were: technology, role of others, tailoring, disease journey and competing priorities. These data will inform further development of ASICA to increase user adherence.

People previously treated for cutaneous melanoma are recommended to conduct monthly total-skin self-examinations (TSSEs) to enable the earliest detection of recurrence or new primaries, but only 20–25% report doing so.<sup>1–3</sup> We developed the Achieving Self-directed Integrated Cancer Aftercare (ASICA) app with patients and clinicians to support monthly TSSE by people previously treated for melanoma.<sup>4</sup> Briefly, ASICA is an app-based digital intervention prompting and guiding TSSEs and enabling users to send descriptions and photographs of any skin concerns to a remote dermatology nurse practitioner.

After refinement, ASICA was subject to a 12-month randomized controlled trial (ClinicalTrials.gov NCT03328247). Overall, the intervention group reported increased TSSE and improved quality of life.<sup>5</sup> Most (57%) of the intervention group submitted details of a concern with most resolved without face-to-face consultation.<sup>5,6</sup> We concluded that ASICA could support increased TSSE by people previously treated for melanoma, a view endorsed by a parallel qualitative study.<sup>7</sup> Based on user feedback a 'mocked-up' smartphone (rather than the original tablet) version of ASICA was developed.

It has been observed, however, that digital healthcare adherence is subject to attrition where a proportion of users stop using the intervention over time, and nonadoption where users do not engage with the intervention at all.<sup>8</sup> Adherence data from the ASICA trial supported this, identifying three distinct trajectories. An 'adherent' group

of participants (41%) who consistently completed monthly TSSEs for 12 months; a 'drop-off' group of participants (36%) who adhered initially but with declining use over 2–6 months and a 'nonadherent' group of participants (24%) who failed to engage with the intervention despite enrolling. This qualitative study explored the perceptions of ASICA users of adherence barriers and facilitators.

#### Report

Qualitative data derived from three sources. Previous trial participants participated in a facilitated focus group (3 attended) or semistructured telephone interviews (11 conducted) and were texted a link to a smartphone 'mock-up' of ASICA to view beforehand. The focus group lasted 98 min and interviews 14–58 min. We also conducted secondary analysis of 13 semistructured interviews (10–45 min) conducted with ASICA users to capture their experiences during the trial. These participants used the tablet version of ASICA and did not view the smartphone 'mock-up'.8 The age range for the 27 participants was 29–86 years of age.

Transcripts were uploaded to NVIVO 1.6.1 and subject to thematic analysis. <sup>10</sup> Five themes emerged: technology; role of others; tailoring; disease journey and competing priorities (see Appendix S1 in the Supporting Information for some illustrative quotes).

The first theme was technology. Several suggested the current interface had limitations that could hinder engagement and suggested improvements, especially developing a smartphone version. Some participants did not use technology routinely and others were unfamiliar with different operating systems. Our current prototype does not include artificial intelligence (AI); however, general concerns about emergent Al technology were viewed as a barrier to engaging with digital healthcare, particularly the robustness of diagnosis and a preference for human contact when worried. Conversely, one younger participant thought Al would enhance future adherence. One user expressed concerns about how personal data could be harvested while using digital healthcare. Other ideas to improve adherence included virtual small group sessions, an easy-to-navigate instructional video, and integrating social media functionality.

The second theme was the role of others. A few participants suggested engaging others would improve motivation and adherence. More than half were helped by other people to perform TSSEs, to check and photograph hard to see body areas or compare between current and previous skin images. Some participants said they were strongly motivated to adhere to the trial to help others in future. Several participants mentioned speaking to the dermatology nurse practitioner by phone and thought this subsequently sustained their adherence.

The third theme was tailoring. Participants thought adherence could improve if the app provided individually salient information but recognized that different people would want different things. Some felt a reminder of why skin checking was important would help. Other participants suggested news about research, information about skin protection products and ultraviolet weather reports would provide motivation. Tailoring monthly prompts and the importance of a reminder that worked for individuals featured prominently. Phone calls, email, autosyncing with calendars, an app-based prompt like food delivery apps, even a physical postcard, were all mentioned. It was also suggested that a prompt could arrive at the wrong time for participants (for example during work, on holiday). One participant felt regular prompts may be off-putting for some users and suggested individuals should be able to set their own schedule of TSSEs.

The fourth theme was disease journey. A third of participants suggested that adherence would likely drop as skin checking became less salient as time went on. They suggested that individuals may have heightened concern in the first few months but would accommodate to their condition over time and feel less need to check. It was noted that ongoing traditional face-to-face follow-up contributed to this process. On the other hand, it was acknowledged that individuals differed and that some may be motivated by ongoing concerns about recurrence, the belief that one annual check was insufficient and a sense of wellbeing produced by having completed the skin check.

The final theme was competing priorities Two-thirds of the participants noted that busy lives, for example work commitments affected adherence. They mentioned that other things take precedence and reduce the priority of skin checking. One participant had disengaged with TSSE during a bereavement. The burden of the task (i.e. having more moles to check) also contributed to disengagement.

Digital technology can support regular TSSEs for people previously treated for melanoma, but more effectively for some than others. Our study sheds light on practical reasons why some people adhered more closely than others with corresponding implications for modification and tailoring. Our data, derived from 27 individuals at different stages of experience highlights several themes with the potential to be addressed in future, for example by simplifying the interface; introducing additional tailoring; encouraging engagement with others; and/or integrating smart scheduling. Participants who were socially deprived were underrepresented in the current sample, but urban and rural dwellers were included. Similarly, the sample included individuals from the adherent and drop-off groups but not any from the nonadherent group. Including individuals from the nonadherent group and other demographics, such as older people will be essential in future research to ensure digital healthcare does not increase health inequalities.

Overall, the information we have obtained from this study, in context with our other data, will inform the detailed modifications we are now making to ASICA.

## Learning points

- Achieving Self-directed Integrated Cancer Aftercare (ASICA), an app-based digital intervention increased regular total-skin self-examination and improved quality of life in people previously treated for melanoma.
- However, adherence varied with a third who adhered optimally but with adherence dropping off in another third and the final third of recruits did not adopt the intervention at all.
- Barriers and facilitators were explored in interviews and a focus group with app users.
- Important barriers to adherence were interface problems, orientation towards technology, lack of support from others and competing priorities.
- Important facilitators of adherence were technology receptiveness, having support from others, tailoring to individual needs and being more recently diagnosed.
- These barriers and facilitators are now informing further development of the ASICA intervention.

# **Acknowledgements**

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#### Funding sources

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#### Conflicts of interest

The authors declare no conflicts of interest.

### Data availability

The data underlying this article are available upon request from the corresponding author.

#### **Ethics statement**

Ethical approval: Ethical approval for the ASICA trial was granted by North of Scotland Research Ethics Committee in April 2017 (17/NS/0040). Approval for the sub-study was granted by North of Scotland Research Ethics Committee in January 2022 (17/NS/0040). All methods were carried out in accordance with Good Clinical Practice and research governance and quality assurance policies and procedures of the University of Aberdeen. Informed consent: all patients gave written, informed consent for participation and publication.

# **Supporting Information**

Additional Supporting Information may be found in the online version of this article at the publisher's website.

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\*SOTYKTU was studied in two global, Phase 3, randomised, multi-arm clinical studies: POETYK PSO-1 and PSO-2. PASI 75 and sPGA 0/1 vs. placebo at Week 16 were co-primary endpoints.
PASI 75 was defined as ≥75% reduction from baseline in the Psoriasis Area and Severity Index. sPGA was defined as sPGA score of 0 or 1 with ≥2-point improvement from baseline. N numbers: PSO-1: SOTYKTU (n=332); apremilast (n=168), placebo (n=166); PSO-2: SOTYKTU (n=511); apremilast (n=254), placebo (n=255). SOTYKTU delivered superior PASI 75 response rates vs placebo (PSO-1: 58.4% vs. 12.7%, p<0.0001; PSO-2: 53.0% vs. 9.4%, p<0.0001) at Week 16, and superior results achieving clear or almost clear skin (sPGA 0/1) vs. placebo (PSO-1: 53.6% vs. 7.2%, p<0.0001; PSO-2: 49.5% vs. 8.6%, p<0.0001) at Week 16 (co-primary endpoints).<sup>2,3</sup>

<sup>†</sup>Via enzyme inhibition, enzyme induction, or transporter inhibition.<sup>1</sup>

Abbreviations: AE, adverse event; DDI, drug-drug interaction; PASI, Psoriasis Area and Severity Index; sPGA, static Physician's Global Assessment; TYK2, tyrosine kinase 2.

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# SOTYKTU®▼ (deucravacitinib) PRESCRIBING INFORMATION

#### **Great Britain**

Consult Summary of Product Characteristics (SmPC) before prescribing. This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

PRESENTATION: Film-coated tablet containing 6 mg of

**INDICATION:** Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

DOSAGE AND ADMINISTRATION: Treatment should be initiated under the guidance and supervision of a physician experienced in the diagnosis and treatment of psoriasis. Posology: 6 mg orally once daily. If a patient shows no evidence of therapeutic benefit after 24 weeks, treatment discontinuation should be considered. The patient's response to treatment should be evaluated on a regular basis. Special populations: Elderly: No dose adjustment is required in elderly patients aged 65 years and older. Clinical experience in patients ≥ 75 years is very limited and deucravacitinib should be used with caution in this group of patients. Renal Impairment: No dose adjustment is required in patients with renal impairment, including end stage renal disease (ESRD) patients on dialysis. Hepatic impairment: No dose adjustment is required in patients with mild or moderate hepatic impairment. Deucravacitinib is not recommended to be used in patients with severe hepatic impairment. Paediatric population: The safety and efficacy of deucravacitinib in children and adolescents below the age of 18 years have not yet been established. No data are available. Method of administration: For oral use. Tablets can be taken with or without food. Tablets should be swallowed whole and should not be crushed, cut, or chewed.

**CONTRAINDICATIONS:** Hypersensitivity to the active substance or to any of the excipients (see SmPC). Clinically important active infections (e.g. active tuberculosis).

WARNINGS AND PRECAUTIONS: Infections: Treatment should not be initiated in patients with any clinically important active infection until the infection resolves or is adequately treated. Caution should be exercised when considering the use in patients with a chronic infection or a history of recurrent infection. Patients treated with deucravacitinib should be instructed to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops a clinically important infection or is not responding to standard therapy, monitor carefully and deucravacitinib should not be given until the infection resolves. Pre-treatment evaluation for tuberculosis (TB): Prior to initiating treatment with deucravacitinib, patients should be evaluated

for TB infection. Deucravacitinib should not be given to patients with active TB. Treatment of latent TB should be initiated prior to administering deucravacitinib. Anti-TB therapy should be considered prior to initiation of deucravacitinib in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Patients receiving deucravacitinib should be monitored for signs and symptoms of active TB. Malignancies\*: Malignancies, including lymphomas and non-melanoma skin cancer (NMSC), were observed in clinical studies with deucravacitinib. Limited clinical data are available to assess the potential relationship of exposure to deucravacitinib and the development of malignancies. Long-term safety evaluations are ongoing. The risks and benefits of deucravacitinib treatment should be considered prior to initiating patients\*\*. Major adverse cardiovascular events (MACE), deep venous thrombosis (DVT) and pulmonary embolism (PE)\*: An increased risk was not observed in clinical trials with deucravacitinib. Long-term safety evaluations are ongoing. The risks and benefits of deucravacitinib treatment should be considered prior to initiating patients\*\*. Immunisations: Consider completion of all age-appropriate immunisations according to current immunisation guidelines prior to initiating therapy. Use of live vaccines in patients being treated with deucravacitinib should be avoided. Excipients: Contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose galactose malabsorption should not take this medicinal product. Contains less than 1 mmol of sodium (23 mg) per tablet, essentially 'sodium-free'. \*serious. \*\*It is not known whether tyrosine kinase 2 (TYK2) inhibition may be associated with the adverse reactions of Janus Kinase (JAK) inhibition. In a large randomised active-controlled study of a JAK inhibitor in rheumatoid arthritis (RA) patients 50 years and older with at least one additional cardiovascular risk factor, a higher rate of malignancies (particularly lung cancer, lymphoma and NMSC). a higher rate of MACE (defined as cardiovascular death, non-fatal myocardial infarction and non-fatal stroke), and a dose dependent higher rate of venous thromboembolism (including DVT and PF) were observed with a JAK inhibitor compared to TNF inhibitors.

**INTERACTIONS:** Deucravacitinib does not have any known clinically relevant drug interactions. Refer to SmPC for full details.

PREGNANCY AND LACTATION: <u>Pregnancy</u>: There is a limited amount of data on the use of deucravacitinib in pregnant women. As a precautionary measure, it is preferable to avoid the use of deucravacitinib during pregnancy. <u>Breast-feeding</u>: It is unknown whether deucravacitinib/metabolites are excreted in human milk. A risk to the newborns/infants by breast-feeding cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from deucravacitinib

therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman. Fertility: The effect of deucravacitinib on human fertility has not been evaluated.

UNDESIRABLE EFFECTS: The most commonly reported adverse reaction is upper respiratory infections (18.9%), most frequently nasopharyngitis. The longer-term safety profile of deucravacitinib was similar and consistent with previous experience. Very common (≥ 1/10): Upper respiratory infections\*\*\*\* (including nasopharyngitis, upper respiratory tract infection, viral upper respiratory tract infection, pharyngitis, sinusitis, acute sinusitis, rhinitis, tonsillitis, peritonsillar abscess, laryngitis, tracheitis, and rhinotracheitis). Common (≥ 1/100 to < 1/10): Herpes simplex infections\*\*\*\* (including oral herpes, herpes simplex, genital herpes, and herpes viral infection), Oral ulcers (including aphthous ulcer, mouth ulceration, tongue ulceration, and stomatitis), Acneiform rash (including acne, dermatitis acneiform, rash, rosacea, pustule, rash pustular, and papule), Folliculitis and Blood creatine phosphokinase increased. Uncommon (≥ 1/1,000 to < 1/100): Herpes zoster\*\*\*. Refer to SmPC for full details on adverse reactions.

\*\*\*serious adverse drug reaction

#### LEGAL CATEGORY: POM

#### MARKETING AUTHORISATION NUMBER and BASIC NHS

PRICE: PLGB 15105/0179: Carton of 28 film-coated tablets 6 mg NHS price: £690.00; Carton of 84 film-coated tablets 6 mg NHS price: £2070.00.

MARKETING AUTHORISATION HOLDER: Bristol-Myers Squibb Pharma EEIG, Plaza 254, Blanchardstown Corporate Park 2, Dublin 15. D15 T867, Ireland.

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medical.information@bms.com or 0800 731 1736 (Great Britain). **DATE OF PREPARATION:** May 2023

ADDITIONAL INFORMATION AVAILABLE ON REQUEST

Approval code: 1787-GB-2300080

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