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# Process evaluation of a multi-centre randomized clinical trial of substituting surgical excisions of low-risk basal cell carcinomas from secondary to primary care



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# Process evaluation of a multi-centre randomized clinical trial of substituting surgical excisions of low-risk basal cell carcinomas from secondary to primary care

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## Article Summary – Strengths and limitations of this study

- This process evaluation uses complementary descriptive quantitative measures and qualitative measures at different time points during the course of the trial.
- It provides essential in-depth insight into general practitioners' exposure to the intervention, implementation of the intervention, and their experiences with the intervention and trial.
- Future trials may benefit from thorough qualitative barrier analysis among all involved stakeholders before the onset as well as during the course of the trial.


## Abstract

**Objectives**

In 2016 the SKINCATCH Trial, a clustered multi-centre randomized trial, was initiated to assess whether low-risk basal cell carcinomas (BCCs) can be treated by general practitioners (GPs) without loss of quality of care. The trial intervention consisted of a tailored 2-day educational course on skin cancer management. The aim of this process evaluation was to investigate GPs' exposure to the intervention, implementation of the intervention, and experiences with the intervention and trial.

**Research design and methods**

Data on exposure to the intervention, implementation and experiences was obtained at several moments during the trial. Complementary quantitative components (i.e. surveys, database analysis, medical record analysis) and qualitative components (i.e. interviews and focus groups) were used. Quantitative data were analysed using descriptive statistics; qualitative data were summarized (barrier interviews) or audio-recorded, transcribed verbatim and thematically analysed using Atlas.Ti (focus groups).

**Results**




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Following a 100% intervention *exposure*, results concerning the *implementation* of the trial showed that aside from the low inclusion rate of patients with low-risk BCCs (n=54), even less excisions of low-risk BCCs were performed (n=40). Although the intervention was *experienced* as highly positive, several barriers were mentioned regarding the trial including administrative challenges, lack of time and high workload of GPs, low volume of BCC patients and patients declining to participate or requesting a referral to a dermatologist.

**Conclusions**

Although GPs' participation in the highly valued training was optimal, several barriers may have contributed to the low inclusion and excision rate of low-risk BCCs. While some of the issues were trial-related, other barriers such as low patient-volume and patients requesting referrals are applicable outside the trial setting as well. This may question the feasibility of substitution of surgical excisions of low-risks BCCs from secondary to primary care in the current Dutch setting.

**Trial registration number**: Trial NL5631 (NTR5746)

## Key words (3-10)

Skin cancer, basal cell carcinoma, dermatology, primary care, general practitioner, substitution of care

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## Background

Health care is becoming increasingly expensive with rising percentages of the gross domestic product spent on health care.[1-3] Since research has shown health systems with stronger primary care tend to have lower health care costs, initiatives such as substitution of hospital care towards primary care are increasingly developed and experimented with worldwide.[4-13] The main goal of these initiatives is to maintain the affordability, and thus sustainability, of healthcare. Furthermore, it is a means to provide more easily accessible care closer to the patients' home. However, not every type of care may be suitable for substitution towards primary care. Whether a particular type of care is deemed appropriate for substitution depends on various disease and care specific factors, such as high-volume and being low-complex care, and the support of different stakeholders including general practitioners (GPs), medical specialists, and patients.[5]

One type of care that has been conceived as a potential candidate for substitution of hospital care towards primary care is low-risk skin cancer care.[5 14] In the Netherlands, as in several other countries such as the UK and Australia, GPs have a gatekeeper function.[5 15 16] Consultations are mainly patient driven, and GPs, who until recently did not have a related primary care guideline, determine whether patients need access to secondary and tertiary healthcare.[17] A substantial proportion of patients with a BCC (60% in a comprehensive Dutch primary care database analysis) are referred to the dermatologist.[18-21] The idea of substituting low-risk skin cancer care to GPs is reflected in the recently published guideline 'suspicious cutaneous lesions' of the Dutch College of General Practitioners, which includes recommendations for GPs on the diagnosis and treatment of low-risk BCCs.[17] Particularly, low-risk basal cell carcinomas (BCCs) (i.e., non-aggressive histological subtypes, low-risk locations and size <2 cm) are relatively easy to diagnose and treat. Minor surgery can be performed in primary care offices, and innovations such as teledermatology can support GPs.[22 23]

In 2016 the SKINCATCH Trial (SKIN Cancer And Tumour Health Care) was initiated to assess whether low-risk BCCs can be treated by GPs without loss of quality of care. The study design was a multi-



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centre cluster randomized non-inferiority trial, in which the intervention concluded a tailored 2-day educational course on skin cancer management. Participating GPs showed great enthusiasm and interest at the start of the trial [14], and although the patient inclusion rate of all skin tumours suspicious for skin cancer was consistent with the researchers' expectations, the inclusion rate of low-risk BCCs (primary outcome) lagged far behind.

Therefore, a process evaluation was conducted alongside the trial. A process evaluation is crucial for providing insight in to what extent the trial intervention was actually implemented, how it was experienced by study participants and whether the intervention is feasible in daily practice.[24 25] The results can be used to guide the implementation of similar care substitution initiatives.[24] The aim of our process evaluation was, therefore, to assess GPs' exposure to the intervention, implementation of the intervention, and experiences with the intervention and trial.

## Methods

### *Description of SKINCATCH Trial*

The SKINCATCH Trial (see Figure 1) was initiated based on the hypothesis that conventional excision of low-risk BCC could be performed by GPs in a primary care setting while maintaining the same quality of care. The study design was a multi-centre cluster randomized non-inferiority trial, with GP practices (including group practices) being included as clusters. These clusters were randomized into two parallel arms: the intervention group, which was trained before starting the trial, and the care-as-usual group. Main outcomes included the histological completeness rate of low-risk BCC excisions by GPs in the intervention group compared to dermatologist (primary outcome), diagnostic accuracy of GPs regarding skin tumours, cost-effectiveness of the intervention and treatment and patient reported outcomes regarding preferences and cosmetics (secondary outcomes) (see Table 1).

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The GPs in the intervention group were offered an extensive training in BCC (and skin tumour) management consisting of a tailored 2-day educational course including hands-on surgical training in cadaveric workshops. The GPs in the care-as-usual group did not receive the 2-day educational intervention and were asked to provide skin cancer care the way they were used to. As compensation, they were offered the same BCC management training after completion of the trial. Eligible patients (i.e., all patients with a skin tumour suspicious for malignancy) were to be included in the trial during the period February 2016 to May 2018. Included patients were asked to complete questionnaires at start of their treatment, and 3 and 6 months post-treatment.

**Figure 1: Overview of SKINCATCH Trial design.**

*Abbreviations: BCC, basal cell carcinoma; CEA, cost-effectiveness analysis; GP, general practitioner; PROMs, patient reported outcome measures.*

The power analysis for the primary outcome was based on a t-test of the proportion of histological completeness of the physicians (GPs and dermatologists), where the physician is the unit of analysis. We expected 5 eligible patients in the non-inferiority part of the trial per GP per year, which was based on national incidence rates and a prior GP survey.[26 27] Using a non-inferiority margin of 5% (based on a clinically accepted margin) and a one-sided significance level of 2.5%[28], a sample size of 45 GPs per group (90 GPs total) was required to obtain a power of 80%. This sample size was increased to 129 GPs to account for (1) the possibility of drop-outs of GPs, and (2) the effect of within-practice correlations of the GPs.

**Table 1: Interventions, recommendations and outcome measures of the SKINCATCH Trial.**

| | |
|---|---|
| Main components of interventions for intervention group | A tailored 2-day educational course regarding the diagnosis and management of skin cancer with a focus on BCCs including hands-on surgical training (cadaveric workshops) |
| | An interactive 20 minute e-learning for GPs, which was available at all times during the trial |
| Main recommendations for low-risk BCC care to be performed by GPs in intervention group | When a skin tumour is suspicious for a malignancy, a biopsy should be performed |
| | If the histopathological examination confirms a low-risk BCC, the GP should perform the excision with adequate margins |



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| | |
|---|---|
| | If the histopathological examination shows a high-risk BCC or other type of skin cancer, the GP should refer the patient to the dermatologist |
| Main outcome measures | Histopathological completeness rate of low-risk BCC excisions by GPs in the intervention group compared to dermatologists |
| | Diagnostic accuracy of skin tumours |
| | Patient reported outcome measures concerning preferences on treating physician and cosmetic results of the received treatment |
| | Cost-Effectiveness Analysis |

*Abbreviations: BCC, basal cell carcinoma; GP, general practitioner.*

A total of 600 patients with a suspicious skin tumour were included in the trial; 316 patients were included by the GPs in the intervention group and contained 54 patients with a low-risk BCC (9% of the needed sample size for sufficient statistical power [n=600]). As recruitment of removed BCCs was so low, we are unable to report on the primary outcome of the trial (histological completeness rate of low-risk BCC excisions by GPs in the intervention group compared to dermatologists). The process evaluation presented in this paper was based on this low inclusion rate of low-risk BCCs.

**Ethics, consent and permissions**

Ethical approval for the trial study was granted by the medical ethics committee of the Erasmus University Medical Centre in Rotterdam (MEC-2015-492). All participants have provided written informed consent. The SRQR guidelines were applied, as far as applicable. These guidelines provide a tool for the transparent reporting of qualitative studies.[29]

## *Design process evaluation*

In designing this process evaluation we used the framework of Hulscher et al.[24] to gain insight into the processes responsible for the (variation in) results in the target group. Data on exposure to the intervention, implementation of the intervention, and experiences with the intervention and trial were obtained. We used both quantitative and qualitative components, which are described in detail below.

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## *Data collection, outcome measures and analyses*

**Surveys**

Two types of surveys were conducted among participating GPs during the course of the trial to assess their *exposure* to the intervention and their *experiences with the intervention and trial*: a training evaluation survey and an online trial evaluation survey. Participation in each of the surveys was voluntary.

Training evaluation survey – After completing the pre-study training all GPs were asked to complete a survey to evaluate the training. With this survey, both their *exposure to and experiences with the training* were assessed. The survey consisted of 8 statements (7 statements on the content of the training, and 1 statement on the organisation of the training) using a five-point Likert-scale ranging from *strongly disagree* to *strongly agree* (Appendix A).

Trial evaluation survey – Ten months after the start of the trial, an online survey was sent to all participating GPs to further explore their *experiences with the trial*. The survey consisted of 4 multiple-choice questions, focussing on experiences with the trial and assessing the perceived barriers (Appendix B).

Training and trial evaluation surveys were analysed separately using SPSS 24.0 statistical software.

**Database analysis**

To gain insight into *the implementation of the intervention* and more specifically the low inclusion rate of BCC patients, a database analysis at the end of the inclusion period was performed investigating the number of inclusions for the primary outcome measure of the trial (i.e. histological completeness of low-risk BCC excisions) based on the paper or digital case report forms (CRF)(i.e., OpenClinica).[30] The CRF included (among others) information on tumour characteristics (e.g., size and location), the histopathological diagnosis of the skin tumour and whether or not the GP performed a surgical excision. The CRFs in OpenClinica were exported to and analysed with SPSS 24.0 statistical



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software. Descriptive statistics were used to assess the number of performed low-risk BCC surgical excisions as compared to the number of included low-risk BCCs.

**Medical record analysis**

A medical record analysis was performed to further explore the *implementation of the intervention* by obtaining quantitative information regarding the number of potential eligible patients and potential eligible excisions. This analysis was performed among 7 randomly selected GPs in two primary care practices, participating in the intervention group of the trial. All GP records from February 2016 to February 2017 were screened for eligible patients by a GP practice healthcare assistant using International Classification of Primary Care (ICPC) codes for skin tumours (Appendix C). Information was obtained on number of patients, clinical diagnosis of the GP, size of the tumour, localisation of the tumour, and choice of treatment. In case of histopathological examination additional information was obtained on histopathological diagnosis from the biopsy and/or excision, and histological completeness in case of surgical excision. If the patient was referred to secondary care information was obtained on clinical or histopathological diagnosis. Descriptive statistics were used to assess the GPs' management of eligible patients.

**Telephonic 'barrier' interview**

Six months after the initiation of the trial, telephonic interviews were conducted by one of the researchers (EN) to identify GPs' *experiences with the trial* in terms of perceived barriers regarding the inclusion of patients. We invited GPs from both arms either with no inclusions or one or more inclusions to participate. After 12 interviews with GPs in the intervention group and 10 GPs in the care-as-usual group no new barriers emerged. The semi-structured interviews were conducted between August and November 2016. The data was analysed by the researcher conducting the telephonic interview (EN), noting reported elements during the interview and descriptively summarizing the main barriers afterwards.



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**Focus groups**

Three focus groups were conducted between December 2017 and March 2018 to gain an in-depth understanding of GPs' *experiences with the intervention and the trial*. Focus groups were chosen as these facilitate interaction between participants, enabling us to identify the GPs' views on substitution of care, and their experiences with the trial.[31-33] All GPs participating in the trial were invited by email, containing an information leaflet about the qualitative evaluation study. GPs could register for one of the three organized focus groups by contacting one of the researchers.

The sessions were moderated by an experienced independent qualitative researcher (ML) and an assistant, both not being involved in the trial. One of the SKINCATCH Trial researchers (EN) was present during the focus groups, but only to answer substantive questions regarding the trial.

In each focus group, the discussion was semi-structured using a predefined topic list consisting of two separate parts: general views on substitution of care (part 1) and GPs' experiences with the trial (part 2). The current study focusses on the latter part (Appendix D). Results on their general views on substitution of care have been described elsewhere.[14]

All focus groups were audio-recorded with consent of participants. Subsequently, the audio tapes were transcribed verbatim and imported to Atlas.ti (version 8 for Windows) for analysis.

Two researchers (EN, ML) independently openly-coded the first transcript after which the obtained codes were discussed and a preliminary coding scheme was developed. Next, all transcripts were coded by one researcher (EN or ML) and subsequently checked by a second researcher (EN or ML). Differences were discussed and refined until agreement was reached, and new codes were added when needed. The initial coding phase was followed by the phase of constant comparison.[31] Different codes were compared and the relationship between codes were explored to detect emerging themes.



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# Results

## *Participants*

A total of 128 GPs from 90 different primary care practices were included for randomisation (Table 2). One GP in the intervention group, and 22 GPs in the care-as-usual group dropped out. Most drop outs occurred within 3 months after the start of the trial. Reported reasons mostly concerned lack of time and personal illness. All 128 GPs were included for the database analysis, and a subgroup of 7 GPs (12%) of the intervention group were included for the medical record analysis. See Table 2 for more information on the participants of the different quantitative and qualitative components. For further details regarding the focus groups see Supplementary table S1.

**Table 2: Participants (GPs) of the SKINCATCH Trial and each of the components of the process evaluation**

| *SKINCATCH Trial* | Intervention group (n=58) | Care as usual group (n=70 |
|---|---|---|
| Male, n(%) | 32 (54) | 33 (47) |
| Drop outs, n(%) | 1 (2) | 22 (31) |
| | | |
| *Quantitative components*, n(%) | | |
| Database analysis | 58 (100) | 70 (100) |
| Medical record analysis | 7 (12) | N/A |
| Training evaluation survey | 57 (98) | N/A |
| Trial evaluation survey | 24 (41) | 36 (51) |
| | | |
| *Qualitative components*, n(%) | | |
| Telephonic 'barrier' survey | 12 (21) | 10 (14) |
| Focus groups | 9 (16) | 8 (11) |
| Focus group 1 (n=8) | 4 (50) | 4 (50) |
| Focus group 2 (n=5) | 2 (40) | 3 (60) |
| Focus group 3 (n=4) | 3 (75) | 1 (25) |

*Abbreviations: GP, general practitioner*

## *Exposure to the intervention*

All GPs in the intervention group (n=58) completed the extensive 2-day training program. Regarding the e-learning, it was not possible to measure the exposure quantitatively; it could be openly accessed by GPs at all times. The focus groups suggested that a wide variation existed regarding the



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exposure to the e-learning. Whereas some GPs stated to have gone through the files, others reported not remembering it have been offered or not to have opened it due to time restrictions.

### *Implementation of the intervention*

Of the total of 600 patients with suspicious skin tumours included in the trial, 316 patients were included by the GPs in the intervention group, containing 54 patients with a low-risk BCC (9% of the needed sample size for sufficient statistical power [n=600]). Furthermore, the GPs in the intervention group performed 95 surgical excisions of skin tumours in total, of which 40 concerned a low-risk BCC. In the care as usual group 29 of the 284 included patients concerned patients with histopathological confirmed low-risk BCCs.

The medical record analysis of potentially eligible BCCs patients in one year among 7 GPs resulted in 448 potential patients. After manual extraction by two of the authors (EN, KR), 35 confirmed BCC patients remained of which 16 were low-risk BCC. Three BCCs (19%) were excised by two of the seven GPs; the remaining 13 tumours were not excised by the GP. Reported reasons in the medical records were: preference for topical treatment (n=2), patient preference for dermatologist (n=1), referral due to melanoma in differential diagnosis (n=1), coinciding melanoma (n=1), not reported in medical record (n=8).

### *Experiences with the intervention and trial*

#### ***Experiences with the intervention***

*Training evaluation survey* - The training was generally evaluated positively by the GPs (Figure 2); 95% (n=54/57) indicated to have found the training useful and 93% (n=53/57) indicated they would recommend the training among colleagues. All GPs (strongly) agreed with the statement the training would change the way they manage skin cancer, and 82% (n=47/57) confirmed that it was clear to



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them what was expected regarding their participation in the trial. For further details on the training evaluation survey see Supplementary figure S1.

**Figure 2: Results from the training evaluation survey.**

*Focus groups* – The focus groups confirmed that the GPs were highly positive about the training. Some reported it to be the best training they have ever had. According to the GPs it offered them guidance in managing skin tumours in general, and it was particularly useful to learn techniques for minor surgery hands-on. GPs indicated to feel more empowered to extend their services regarding skin tumour management in daily practice. However, some GPs did mention that with time passing they returned to old patterns. According to the GPs, the training may not have been enough for all GPs to change their role in the management of skin tumours. Furthermore, according to some GPs the participation in the trial caused them to diminish their role in skin cancer management as they were used to performing minor surgery on high(-er) risk skin cancers (e.g., BCCs located in the face), which was restricted by the study protocol. Regarding the e-learning, the few GPs who used the e-learning were generally positive and reported it was fun to do.

***Experiences with the trial***

*Trial evaluation survey* – Reported reasons for the low number of included (BCC) patients in the trial concerned lack of time (n=34) and realizing the patients' eligibility afterwards (n=27), patients rejected participation (n=11), not understanding the different study forms (n=5), the trial restricts me on performing excisions due to trial recommendations (n=3), the GP being afraid to perform minor surgery (n=1) and having to treat the patient different from what they were used to (n=1). A smaller group of GPs (22%) agreed with the statement that it would make it easier for them to only include patients with a low-risk BCC rather than all skin cancers, and the largest part (n=44 [73%]) disagreed



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with the option of clustering consultation hours for skin cancer patients for GPs individually to make patient recruitment more easy.

*Telephonic 'barrier' interview* – During the telephonic interview six barriers were identified. Main perceived barriers reported by the GPs concerned ambiguity regarding eligibility criteria of patients, and lack of clarity regarding the trials' CRFs. GPs indicated that they expected one of the researchers to visit their practices for one-on-one explanation on the forms. Further perceived barriers included the trial not being a priority, the inclusion process being too time-consuming, difficulty retaining information over time, and discouragement due to refusal of patients or skin tumours appearing high risk.

*Focus groups* –GPs' experiences regarding the trial varied. Whereas some GPs were positive about the trial and managed to include patients (up to 53), others reported rather negative experiences. Several barriers were identified which may have contributed to the relatively low inclusion rate (both in general as well as concerning low-risk BCCs). First, *administrative challenges* related to the inclusion of patients to the trial were reported as a barrier. According to the GPs, the inclusion procedure (informed consent procedure and CRF) was difficult to integrate in daily practice with several study forms needed to be completed at different times during the treatment course of the patient. GPs reported this to be difficult and too time-consuming. However, GPs lacked suggestions on how to improve these administrative challenges as they know it is crucial for data collection. Some GPs reported to have experienced the start of the trial as rather confusing; they stated study forms were not immediately present, and that both the start-date for inclusion as well as the eligibility criteria were not clear. Others were more positive and reported to have found a way of structuring it for themselves, and commented that inaccuracies were picked up well by the researchers. The online CRF application (i.e., OpenClinica) was variably received by the GPs, though it was specifically designed for the trial in an attempt to facilitate the GPs in data registration. Some GPs reported it to be not user-friendly and continued using the paper forms, while others stated it to



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be of great help. Suggestions on reducing the administrative challenges included having researchers collect the data themselves by visiting the GPs' practices and using an automated digital data collection programme.

Another reported barrier related to the administrative barrier, was a perceived *lack of time and high workload* to include patients. According to the GPs, this was related to cramped consultation hours, being behind schedule, and patients presenting multiple problems during consultation with their GP in which the skin tumour was not perceived as the main issue. As a result of the lack of time and high workload, GPs were more hesitant to recruit patients as this would consume additional time.

A third barrier as reported by the GPs was the *low volume of eligible patients* seen in practice. GPs reported to only see a small number of low-risk BCC annually. Some also stated to have seen less BCC patients during the course of the trial than anticipated, for reasons not clear.

A fourth barrier reported were *patients declining or refusing to participate* in the trial. According to the GPs, some patients did not want to participate due to the difficulty and large amount of information they had to read upon participation request, and things needed from them after inclusion (i.e., questionnaires). The GPs further mentioned that especially older patients and patients with a lower IQ often declined to participate.

In addition to the low inclusion rate, the GPs were also asked for possible explanations for the low rate of excisions performed by GPs during the trial. Whereas some GPs indeed reported to have only performed few excisions, others were rather surprised hearing this as it did not align with their own experiences. Reported reasons for the low number of excisions were the low number of BCC patients seen in daily practice, patients requesting a referral to the dermatologist, a lack of time and high workload, having a colleague who performs all the excisions, and the training course not being sufficient to change GPs' behaviour, particularly considering the reported already high workload.



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## Discussion

This evaluation study showed that, although GPs initially showed great enthusiasm towards the concept of substitution[14], and all GPs participated in the highly valued training, several barriers may have contributed to the low inclusion and excision rate of low-risk BCC patients. Some of these barriers seem to be attributable to the trial setting (e.g., administrative challenges, patient recruitment issues), complicating its implementation in daily practice. However, other reported barriers such as high workload, low volume of low-risk BCC patients and patients requesting a referral, apply outside the trial setting as well.

Although several trial-related barriers, such as clear study forms and inclusion criteria, should have been adequately addressed in the current trial, other practical issues such as patient recruitment challenges are commonly reported problems within (multicentre) randomised controlled trials (RCTs) and are difficult to prevent completely.[34-38] Similarly, the reported barrier of lack of time/high workload of GPs seems to be inherently related to GP practices[38-40], and may have further impeded study implementation. To tackle these barriers, targeted interventions to enhance recruitments skills of GPs may be valuable to optimize the feasibility of trial interventions in clinical medical care.[38]

In addition to the trial-related barriers, other reported barriers also apply outside the trial setting and concern the topic of substituting low-risk BCC care towards primary care. Despite high and rising incidence rates of BCCs reported in the literature[27 41], we found that only a small proportion of BCCs can be considered 'low-risk' when taking into account body site, diameter and histological subtype[41-43], which was recently confirmed by Fremlin et al.[42] Aside from the low volume, the number of excisions performed by GPs in the intervention group was even lower. According to the GPs this may have been partly related to the training being insufficient to change GPs' practices. Also, GPs were less inclined to perform a surgical excision when patients requested a referral to a dermatologists, which has been found in previous studies as well.[14 15 44-48] These barriers, related to feasibility, need



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to be addressed, where possible, before assessing whether low-risk BCCs can be treated by GPs without a loss of quality of care.

Indeed, with the patient volume being this low (based on the medical record analysis approximately 2 patients with low-risk BCC per GP per year), it will be challenging, if not impossible, for GPs to obtain and maintain their competencies in low-risk BCC management.[14 42] Particularly in the context of this low patient volume, a one-day training may not be sufficient to acquire the relevant competencies. Offering adequate training in a repetitive setting tailored to the specific needs of each GP may therefore contribute to a better integration of what is learned into daily practice.[49 50] Although this was attempted by offering an e-learning module, the uptake (although variable) seemed to be only minimal. Furthermore, the cost-effectiveness of such interventions may be questioned. Other solutions may focus on organizational changes in primary care such as concentrated substitution.[14] Within this concept GPs refer patients to a colleague GP with noted interest, experience and competence in skin cancer care, thereby clustering these patients within or between practices.[14]

A limitation of our study includes the late conduction of a barrier analysis. Implementation of change is a complex process, and a preceding barrier analysis among all involved stakeholder groups is advocated to increase the success of interventions.[51] By addressing identified barriers prior to the onset of this trial, failure may have been prevented. In addition, such input can serve to promote awareness and stimulate involvement among the target groups, incentivizing more successful adoption at a later stage.[52] However, it is also important to elicit views of stakeholders who already have some experience with the intervention at hand, as this often elicits different types of barriers.[14] Performing a barrier analysis both before the onset of the trial as well as during the trial as part of a process evaluation is therefore advised.

A strength of this study is that we used several complementary evaluation methods, combining both quantitative and qualitative data at different time points during the course of the trial, focusing on



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both the intervention and care-as-usual group. Although only a low number of GPs was included in the medical record analysis and data on the use of the e-learning module was lacking, by using triangulation of data we were able to capture different dimensions of the observed phenomena. As such, our process evaluation provides essential in-depth insight into the trial and the observed outcomes.

## Conclusions

This process evaluation has identified some trial-related as well as more general topic-related barriers that may be responsible for the low inclusion and excision rate of low-risk BCC patients by GPs within the trial. Based on the results of this study, without being able to measure the surgical effectiveness of GPs, the feasibility of substituting low-risk BCC care from secondary to primary care in the current setting should be questioned. Future trials on care substitution may benefit from thorough qualitative barrier analyses among all involved stakeholders, before onset as well as during the course of the trial, to increase the likelihood of successful implementation.

**List of abbreviations**

BCC, basal cell carcinoma; CRF, case report form; GP, general practitioner; ICPC, International Classification of Primary Care.

## Declarations

### *Ethics approval and consent to participate*

Ethical approval for the SKINCATCH Trial was granted by the medical ethics committee of the Erasmus University Medical Center in Rotterdam (MEC-2015-492). All participants have provided written informed consent.

### *Consent for publication*

Not applicable.



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## *Availability of data and material*

The data that supports the findings of this study are available from the medical ethics committee of the Erasmus University Medical Center in Rotterdam (Contact: Interview study reference number MEC-2016-204 and Focus group study reference number MEC-2015-492), but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of the medical ethics committee of the Erasmus University Medical Center in Rotterdam.

## *Patient and public involvement*

This research was done without patient involvement. Patients were not invited to comment on the study design and were not consulted to develop patient relevant outcomes or interpret the results. Patients were not invited to contribute to the writing or editing of this document for readability or accuracy.

## *Competing interest*

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: the principal investigator received an institutional grant as financial support from Foundation Achmea Healthcare for the submitted work; no other relationships or activities that could appear to have influenced the submitted work.

## *Funding*

Funding for this research was provided by the Foundation Achmea Healthcare (in Dutch: Stichting Achmea Gezondheidszorg) which had no role in the design, conduct, analysis or interpretation of the study. Award/Grant number is not applicable.

## *Author contributions*

EN, ML, MW, KR, RB, PB, TN involved in the concept and design of the quantitative and qualitative study. EN, ML performed the focus groups. EN, ML, KR involved in quantitative and qualitative data



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acquisition. EN, ML, MW, RB, PB, TN involved in data analysis and interpretation. The paper was written by EN and ML, and was critically revised by all authors. All authors read and approved the final manuscript.


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## References


1. Alberto M, David M, Luca L, et al. Future trends in health care expenditure. 2017 doi: doi:https://doi.org/10.1787/247995bb-en
2. OECD. Better Ways to Pay for Health Care2016.
3. Mackenbach JP. [What are the health benefits of the most expensive healthcare system in Europe?]

Wat levert de duurste gezondheidszorg van Europa ons op? *Ned Tijdschr Geneeskd* 2015;159:A9433. [published Online First: 2015/08/27]
4. de Jong J, Korevaar J, M. K, et al. Substitution potential between primary and secondary health care. www.nivel.nl: NIVEL, 2016:50.
5. Van Dijk C, Korevaar J, De Jong J, et al. Room for substitution? Shift from secondary to primary care. . NIVEL: NIVEL, 2013:109.
6. van Hoof SJ, Kroese ME, Spreeuwenberg MD, et al. Substitution of Hospital Care with Primary Care: Defining the Conditions of Primary Care Plus. *Int J Integr Care* 2016;16(1):12. doi: 10.5334/ijic.2446 [published Online First: 2016/09/13]
7. van Hoof SJ, Spreeuwenberg MD, Kroese ME, et al. Substitution of outpatient care with primary care: a feasibility study on the experiences among general practitioners, medical specialists and patients. *BMC Fam Pract* 2016;17:108. doi: 10.1186/s12875-016-0498-8

10.1186/s12875-016-0498-8 [pii] [published Online First: 2016/08/11]
8. Fortney JC, Steffick DE, Burgess JF, et al. Are Primary Care Services a Substitute or Complement for Specialty and Inpatient Services? *Health Services Research* 2005;40(5p1):1422-42. doi: doi:10.1111/j.1475-6773.2005.00424.x
9. Laurant M, Reeves D, Hermens R, et al. Substitution of doctors by nurses in primary care. *Cochrane database Syst rev* 2005;2(2):CD001271.
10. Martínez-González NA, Djalali S, Tandjung R, et al. Substitution of physicians by nurses in primary care: a systematic review and meta-analysis. *BMC Health Services Research* 2014;14(1):214. doi: 10.1186/1472-6963-14-214
11. Weller DP. Workforce substitution and primary care. *Med J Aust* 2006;185(1):8-9. doi: wel10579_fm [pii] [published Online First: 2006/07/04]
12. Yong CS. Task substitution: the view of the Australian Medical Association. *Med J Aust* 2006;185(1):27-8. doi: yon10552_fm [pii] [published Online First: 2006/07/04]




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13. Starfield B, Shi L. Policy relevant determinants of health: an international perspective. *Health Policy* 2002;60(3):201-18. doi: S0168851001002081 [pii] [published Online First: 2002/04/20]
14. Noels EC, Wakkee M, Van den Bos R, et al. Substitution of low risk skin cancer hospital care towards primary care: a qualitative study on views of general practitioners and dermatologists. 2019
15. Greenfield G, Foley K, Majeed A. Rethinking primary care's gatekeeper role. *BMJ* 2016;354:i4803. [published Online First: 2016/09/25]
16. Moreno G, Tran H, Chia ALK, et al. Prospective study to assess general practitioners' dermatological diagnostic skills in a referral setting. *Australasian Journal of Dermatology* 2007;48(2):77-82. doi: doi:10.1111/j.1440-0960.2007.00340.x
17. Baaten GGG, Buis PAJ, Damen Z, et al. NHG-Standaard Verdachte Huidafwijkingen 2017 [Available from: https://www.nhg.org/standaarden/volledig/nhg-standaard-verdachte-huidafwijkingen.
18. van Dijk CE, Verheij RA, Spreeuwenberg P, et al. Minor surgery in general practice and effects on referrals to hospital care: Observational study. *BMC Health Services Research* 2011;11(1):2. doi: 10.1186/1472-6963-11-2
19. Lowell BA, Froelich CW, Federman DG, et al. Dermatology in primary care: Prevalence and patient disposition. *J Am Acad Dermatol* 2001;45(2):250-5. doi: S0190-9622(01)84392-9 [pii]

10.1067/mjd.2001.114598 [published Online First: 2001/07/21]
20. M.E. B-vD, Y.M. W, K. H, et al. Zorg door de huisarts. . *Jaarcijfers 2017 en trendcijfers 2011-2017* 2018 18-07-2018. (accessed 07-11-2018).
21. Wakkee M, Van Egmond S, Louwman M, et al. Opportunities for improving keratinocyte cancer care in primary and specialist care: a Dutch cohort study.
22. Eminovic N, Dijkgraaf MG, Berghout RM, et al. A cost minimisation analysis in teledermatology: model-based approach. *BMC Health Serv Res* 2010;10:251. doi: 1472-6963-10-251 [pii]

10.1186/1472-6963-10-251 [published Online First: 2010/08/27]
23. van der Heijden JP, de Keizer NF, Bos JD, et al. Teledermatology applied following patient selection by general practitioners in daily practice improves efficiency and quality of care at lower cost. *Br J Dermatol* 2011;165(5):1058-65. doi: 10.1111/j.1365-2133.2011.10509.x [published Online First: 2011/07/07]
24. Hulscher ME, Laurant MG, Grol RP. Process evaluation on quality improvement interventions. *Qual Saf Health Care* 2003;12(1):40-6. [published Online First: 2003/02/07]
25. Moore GF, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ : British Medical Journal* 2015;350 doi: 10.1136/bmj.h1258
26. de Vries E, Nijsten T, Louwman MW, et al. [Skin cancer epidemic in the Netherlands]

Huidkankerepidemie in Nederland. *Ned Tijdschr Geneeskd* 2009;153:A768. [published Online First: 2009/12/23]
27. Flohil SC, de Vries E, Neumann HA, et al. Incidence, prevalence and future trends of primary basal cell carcinoma in the Netherlands. *Acta Derm Venereol* 2011;91(1):24-30. doi: 10.2340/00015555-1009 [published Online First: 2011/01/26]
28. Head SJ, Kaul S, Bogers AJ, et al. Non-inferiority study design: lessons to be learned from cardiovascular trials. *Eur Heart J* 2012;33(11):1318-24. doi: ehs099 [pii]

10.1093/eurheartj/ehs099 [published Online First: 2012/05/09]
29. O'Brien BC, Harris IB, Beckman TJ, et al. Standards for reporting qualitative research: a synthesis of recommendations. *Acad Med* 2014;89(9):1245-51. doi: 10.1097/ACM.0000000000000388 [published Online First: 2014/07/01]
30. Cavelaars M, Rousseau J, Parlayan C, et al. OpenClinica. *Journal of Clinical Bioinformatics* 2015;5(1):S2. doi: 10.1186/2043-9113-5-s1-s2
31. Green J, Thorogood N. Qualitative methods for health research. 3rd revised edition ed: Sage Publications Ltd 2014:233-254.



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Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

32. Krueger RA, Casey MA. Focus groups: a practical guide for applied research.: SAGE 2000.
33. Willis K, Green J, Daly J, et al. Perils and possibilities: achieving best evidence from focus groups in public health research. *Australian and New Zealand Journal of Public Health* 2009;33(2):131-36. doi: doi:10.1111/j.1753-6405.2009.00358.x
34. McDonald AM, Knight RC, Campbell MK, et al. What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies. *Trials* 2006;7:9. doi: 1745-6215-7-9 [pii]

10.1186/1745-6215-7-9 [published Online First: 2006/04/11]
35. de Wit NJ, Quartero AO, Zuithoff AP, et al. Participation and successful patient recruitment in primary care. *J Fam Pract* 2001;50(11):976. doi: jfp_1101_09760 [pii] [published Online First: 2001/11/17]
36. van der Gaag WH, van den Berg R, Koes BW, et al. Discontinuation of a randomised controlled trial in general practice due to unsuccessful patient recruitment. *BJGP Open* 2017;1(3):bjgpopen17X101085. doi: 10.3399/bjgpopen17X101085

bjgpopen17X101085 [pii] [published Online First: 2017/10/04]
37. Bower P, Wilson S, Mathers N. Short report: how often do UK primary care trials face recruitment delays? *Fam Pract* 2007;24(6):601-3. doi: cmm051 [pii]

10.1093/fampra/cmm051 [published Online First: 2007/09/18]
38. Foster JM, Sawyer SM, Smith L, et al. Barriers and facilitators to patient recruitment to a cluster randomized controlled trial in primary care: lessons for future trials. *BMC Med Res Methodol* 2015;15:18. doi: 10.1186/s12874-015-0012-3

10.1186/s12874-015-0012-3 [pii] [published Online First: 2015/04/19]
39. Croxson CH, Ashdown HF, Hobbs FR. GPs' perceptions of workload in England: a qualitative interview study. *Br J Gen Pract* 2017;67(655):e138-e47. doi: bjgp17X688849 [pii]

10.3399/bjgp17X688849 [published Online First: 2017/01/18]
40. van den Hombergh P, Kunzi B, Elwyn G, et al. High workload and job stress are associated with lower practice performance in general practice: an observational study in 239 general practices in the Netherlands. *BMC Health Serv Res* 2009;9:118. doi: 1472-6963-9-118 [pii]

10.1186/1472-6963-9-118 [published Online First: 2009/07/17]
41. Verkouteren JAC, Ramdas KHR, Wakkee M, et al. Epidemiology of basal cell carcinoma: scholarly review. *Br J Dermatol* 2017;177(2):359-72. doi: 10.1111/bjd.15321 [published Online First: 2017/02/22]
42. Fremlin GA, Gomez P, Halpern J. Are there sufficient numbers of low-risk basal cell carcinomas to justify general practitioners (family physicians) carrying out basal cell carcinoma surgery? *Clin Exp Dermatol* 2016;41(2):138-41. doi: 10.1111/ced.12718 [published Online First: 2015/07/21]
43. Lomas A, Leonardi-Bee J, Bath-Hextall F. A systematic review of worldwide incidence of nonmelanoma skin cancer. *Br J Dermatol* 2012;166(5):1069-80. doi: 10.1111/j.1365-2133.2012.10830.x [published Online First: 2012/01/19]
44. Bath-Hextall F, Nalubega S, Evans C. The needs and experiences of patients with skin cancer: a qualitative systematic review with metasynthesis. *Br J Dermatol* 2017;177(3):666-87. doi: 10.1111/bjd.15148 [published Online First: 2016/10/25]
45. van Egmond S, Wakkee M, Droger M, et al. Needs and preferences of patients regarding basal cell carcinoma and cutaneous squamous cell carcinoma care: a qualitative focus group study. *Br J Dermatol* 2018 doi: 10.1111/bjd.16900 [published Online First: 2018/06/22]
46. Wammes JJ, Jeurissen PP, Verhoef LM, et al. Is the role as gatekeeper still feasible? A survey among Dutch general practitioners. *Fam Pract* 2014;31(5):538-44. doi: cmu046 [pii]





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10.1093/fampra/cmu046 [published Online First: 2014/08/20]
47. Westert GP, Jeurissen PPT, Assendelft WJJ. Why Dutch general practitioners do not put the squeeze on access to hospital care? *Family Practice* 2014;31(5):499-501.
48. Rotar AM, Van Den Berg MJ, Schafer W, et al. Shared decision making between patient and GP about referrals from primary care: Does gatekeeping make a difference? *PLoS One* 2018;13(6):e0198729. doi: 10.1371/journal.pone.0198729

PONE-D-17-43535 [pii] [published Online First: 2018/06/12]
49. Bluestone J, Johnson P, Fullerton J, et al. Effective in-service training design and delivery: evidence from an integrative literature review. *Human Resources for Health* 2013;11(1):51. doi: 10.1186/1478-4491-11-51
50. Lugtenberg M, Pasveer D, van der Weijden T, et al. Exposure to and experiences with a computerized decision support intervention in primary care: results from a process evaluation. *BMC Fam Pract* 2015;16:141. doi: 10.1186/s12875-015-0364-0

10.1186/s12875-015-0364-0 [pii] [published Online First: 2015/10/18]
51. Grol R, Grimshaw J. From best evidence to best practice: effective implementation of change in patients' care. *Lancet* 2003;362(9391):1225-30. doi: S0140-6736(03)14546-1 [pii]

10.1016/S0140-6736(03)14546-1 [published Online First: 2003/10/22]
52. Grol R, Wensing M. What drives change? Barriers to and incentives for achieving evidence-based practice. *Med J Aust* 2004;180(6 Suppl):S57-60. doi: gro10753_fm [pii] [published Online First: 2004/03/12]

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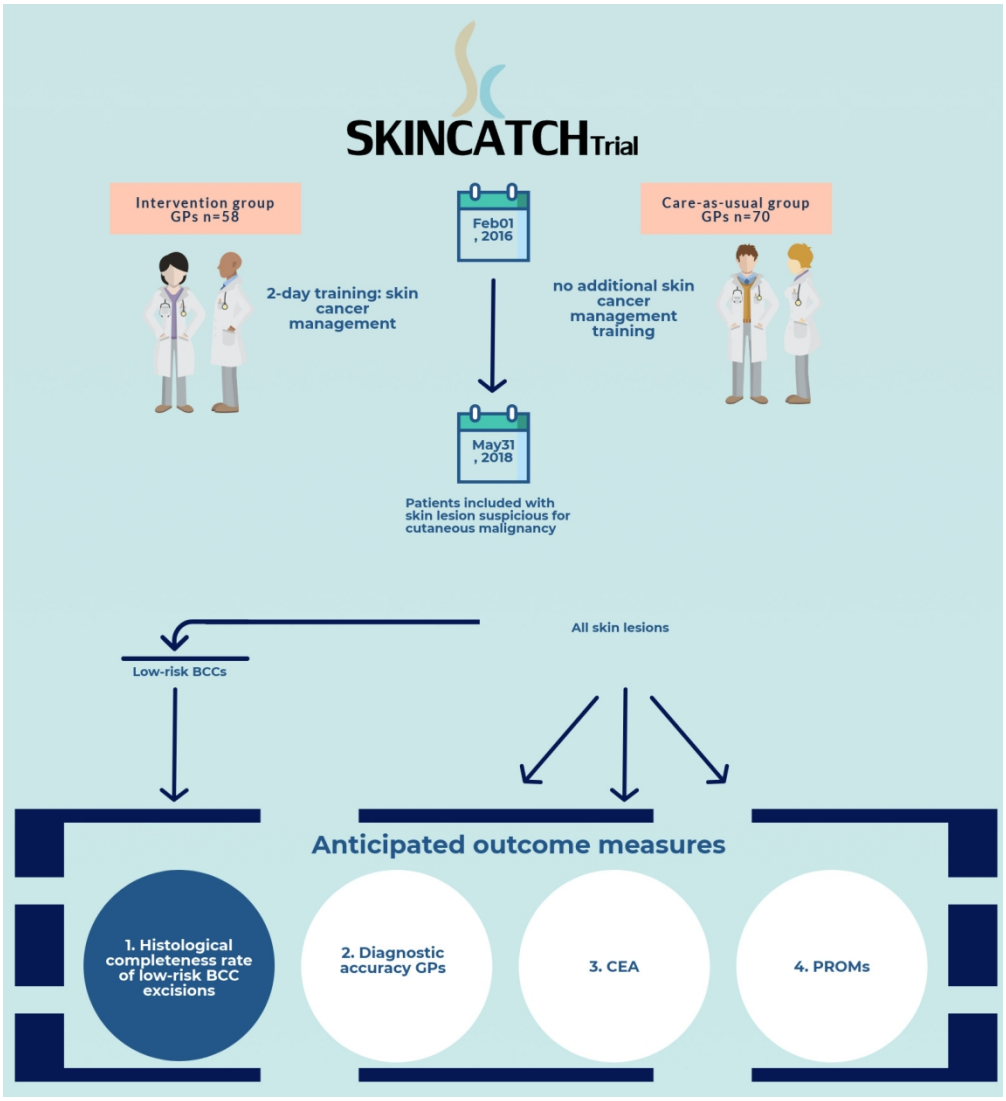


Design SKINCATCH Trial

425x464mm (95 x 95 DPI)



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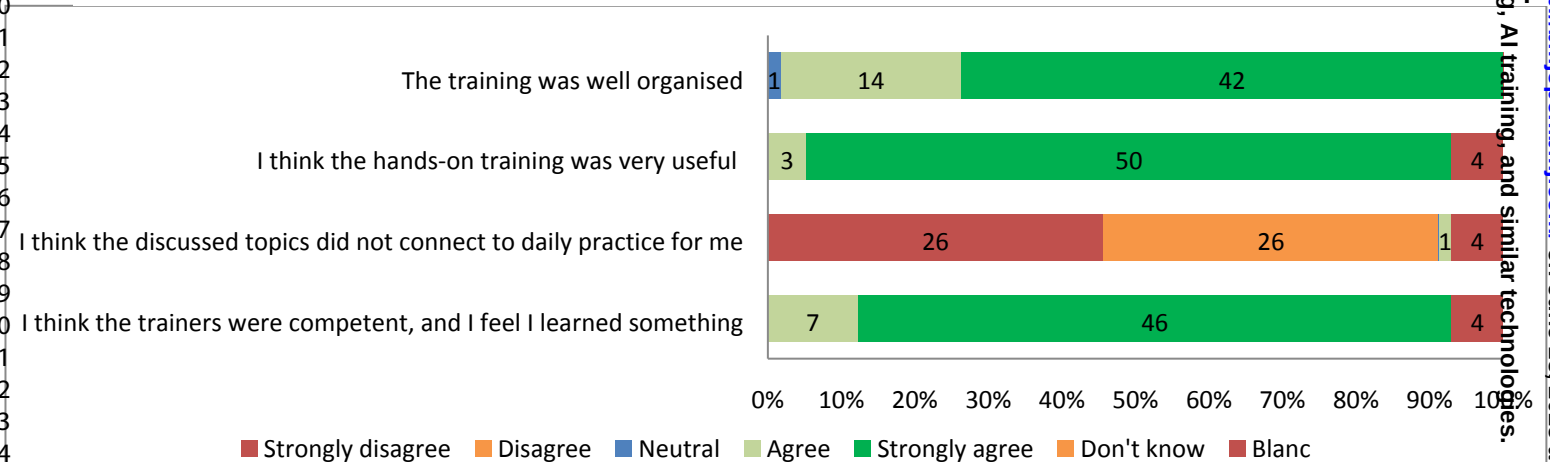
# Supplementary material

## Supplementary tables

| Table S1: Characteristics of GPs participating in the focus group meetings. | | | | |
|---|---|---|---|---|
| | Focus group 1 | Focus group 2 | Focus group 3 | Total |
| Total, n | 8 | 5 | 4 | 17 |
| | | | | |
| Intervention group, n(%) | 4 (50) | 2 (40) | 3 (75) | 9 (53) |
| Male, n(%) | 4 (50) | 2 (40) | 1 (25) | 7 (41) |
| Age, median (IQR) | 51 (43-57) | 49 (41-62) | 36 (35-52) | 49 (39-57) |
| Years of professional experience, median (IQR) | 17 (12-22) | 16 (7-30) | 8 (7-25) | 14 (8-25) |
| Professional environment, n(%) | | | | |
| Individual practice | 2 (25) | 1 (20) | 0 (0) | 3 (18) |
| Duo practice | 2 (25) | 3 (60) | 2 (50) | 7 (41) |
| Group practice or medical centre | 4 (50) | 1 (20) | 2 (50) | 7 (41) |
| | | | | |
| *Abbreviations: GP, general practitioner; IQR, interquartile range* | | | | |

## Supplementary figures

**Figure S1: Additional outcomes of the training evaluation survey.**

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# Appendices

## Appendix A

Training evaluation survey February 2016.

| Statement | Strongly disagree | Disagree | Neither agree or | Agree | Strongly agree | Don't know | No opinion | Not filled in |
|---|---|---|---|---|---|---|---|---|
| 1.I would recommend this training for my colleagues. | | | | | | | | |
| 2. The hands-on part using human specimen was useful. | | | | | | | | |
| 3. The subjects of the training did not reflect daily practice. | | | | | | | | |
| 4. The teachers were competent, I learned something today. | | | | | | | | |
| 5. The training was well organised. | | | | | | | | |
| 6. It was clear was it expected from me as a participant in the trial. | | | | | | | | |
| 7. After this training, I will manage patients with skin cancer differently. | | | | | | | | |
| 8. This training was useful for me. | | | | | | | | |

## Appendix B

Trial evaluation survey November 2016.

Q1: In which study group are you randomized?

a. Intervention group
b. Care as usual group

Q2: How many patients did you include in the trial? ….

Q3: Statement; I do see patients with cutaneous lesions suspicious for a malignancy. The reason I do not include them in the trial are…

a. Lack of time
b. I don't understand the study forms
c. The trial restricts me in skin cancer excisions
d. I am afraid to do skin surgery
e. The patients declined
f. Financial reasons
g. I realize I could have included patients afterwards
h. I don't want to include patient because then I have to treat them differently
i. Other: ….

Q4: Numbers show that GPs should see around 5 patient a year who meet the criteria for low-risk basal cell carcinomas (i.e., <1cm, non-aggressive subtype, primary tumour, low-risk locations).

a. I see less than 5 patients
b. I see 5 patients, but I don't include them



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c. I see more than 5, but I don't include them
d. Other: ….

Q5: Statement; it would be easier for me to only include patients with a skin lesion suspected for low-risk basal cell carcinoma, instead of patient with a skin lesion suspected for a malignancy in general.

a. Agree
b. Disagree
c. It does not matter

Q6: How often would you like to be reminded by us for including patients in the trial?

a. Weekly
b. 2-weekly
c. Monthly
d. Other: ….

Q7: Do you think it would be easier to include patients if these consultation were clustered?

a. Yes
b. No

Q8: Do you have any ideas how we can make it more easy for you? All ideas are welcome! …

Q9: Do you have any final remarks? …

## Appendix C

Medical record analysis.

| Selected ICPC codes | |
|---|---|
| S04 | Localised tumour skin/subcutis |
| S05 | Multiple tumours skin/subcutis |
| S06 | Localised redness/erythema of the skin |
| S21 | .01 Dry skin/ squamae<br>.02 Lichenification/induration |
| S26 | Fear for cancer of the skin/subcutis |
| S77 | .01 Basal cell carcinoma<br>.02 Squamous cell carcinoma<br>.03 Malignant melanoma<br>.04 Kaposi sarcoma |
| S79 | .01 Dermatofibroma |
| S80 | .01 Dysplastic naevus |
| S82 | Naevus/mole |
| S99 | .01 Granuloma pyogenicum<br>.02 Seborrheic keratosis<br>.03 Rosacea<br>.04 Vitiligo<br>.05 Discoid lupus erythematosus<br>.06 Lichen planus<br>.07 Striae |



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| | |
|---|---|
| | .08 Erythema nodosum<br>.09 Keloid<br>.10 Keratoacanthoma<br>.11 Actinic keratosis |

## Appendix D

**Introduction**

- Introduction
- Background and aim of study
- Aim and structure of interview
- Informed consent forms, permission audio-taping, demographic questionnaire to be filled in
-

**Part 1: Experiences with the SKINCATCH Trial**

- General experiences with the trial

**Part 2: Perceived barriers related to the low inclusion rate**

- Perceived barriers related to the low inclusion rate of low-risk BCCs in the trial

**Part 3: Perceived barriers related to the implementation of the trial (low excision rate)**

- Perceived barriers related to the low excision rate

**Part 4: Suggestions to facilitate implementation in the future**

- Practical solutions to facilitate implementation

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**Rebuttal letter [bmjopen-2019-034906]**

Adrian Aldcroft

Editor, BMJ Open

Dear Adrian Aldcroft,

Thank you for the possibility to resubmit our manuscript "A multi-centre randomized clinical trial of substituting surgical excisions of low-risk basal cell carcinomas from secondary to primary care: an evaluation using mixed methods." to the BMJ Open.

We would like to thank the reviewers for their time and effort to review our manuscript. We have addressed the reviewers' comments and hope you will find our revised manuscript acceptable for publication.

Sincerely,

On behalf of all co-authors,

Eline Noels, MD, PhD

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## Reviewer: 1

I feel considerable sympathy for the team involved in this trial and who wrote this paper. What seems a really sensible, well thought out, trial has been a nightmare. So, my comments below shouldn't be seen as a criticism of the team, merely as a way of improving the paper.

1. My main problem stems from the title. It isn't at all clear from the title, and from the abstract, if the paper is doing: a) giving the results of the main trial, plus process evaluation or b) giving the process evaluation alone. It may even be c) giving the results of the process evaluation alone because the main results are so underpowered they'll never be published. I still don't know if I'm reading b) or c)! The title suggests a), compounding the problem.
   So, the team need to decide which it is (they must actually know which it is, but need to be explicit). If it's b) then crucially they need a line in the abstract and main paper saying 'the main results will be published elsewhere'. If it's c) again they have to be honest (and I weep for them) and say quite explicitly, 'recruitment of removed BCCs was so low, we cannot report on the clinical trial outcomes'. I make a lot of this problem, because if it's c) then the message to the reader is 'if you're thinking of a primary care trial, please do a barrier assessment first'.
   Having said all this, the paper is a very thorough process evaluation.

*We thank the reviewer for his/her thoughtful and empathic comments. As the reviewer suggests in option c, in this paper the results of the process evaluation are presented whereas the main results regarding the histological completion rate of low-risk excised BCCs are so underpowered they, unfortunately, will never be published. To clarify this, we have changed the title to state explicitly that it concerns a process evaluation and have also added the text stating that 'recruitment of removed BCCs was so low, we cannot report on the clinical trial outcomes' earlier on in the manuscript (p.7 line 137-139). We agree with the reviewer that one of the main messages of this paper is that it is advocated to perform a barrier analysis prior to the start of primary care trial, which we have elaborately addressed in the discussion section (p.17/18 line 531-545).*

2. I've only one other major comment: the results of the telephone interviews (which apparently reached thematic saturation, so were assessed in a qualitative way) aren't really presented thematically. The three pages 13-15 read more like a list of problems than a qualitative study. that can be improved, perhaps with subheadings.

*We thank the reviewer for his comment and understand some of the results may seem like a list of problems. In this respect we believe it is essential to distinguish the telephonic barrier interviews from the focus groups. The aim of the telephonic barrier interview was in fact to identify a (rapid) list of barriers to further inform the continuation of the trial. The focus groups, however, were performed to gain an in-depth understanding of the perceived barriers and were, as such, thematically analysed. As we used combined multiple methods in this process evaluation, we were forced to describe the results of each method rather concise.*

3. Minor comments: a) there's more to transfer from 2ry to 1ry care than affordability and sustainability. Patients may prefer it (some won't); it can provide superior care (diagnosis and treatment can be performed earlier); and it may be geographically easier for patients to access. So, while I wholly agree with the authors this was worth trying, I think it was more important to study than they suggest.

*We agree with the reviewer that there is more to transfer from 2ry to 1ry care than affordability and sustainability and have therefore revised the sentences in the background section. (p.4, line 69-70)*



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4. b) a further justification for the trial was Peter Murchie's paper on GP-excised melanomas (DOI: 10.3399/bjgp13X670697). Inadvertent melanoma removal was not harmful - which should have eased some of the medico-legal and clinical anxieties.

*Although we are familiar with the paper of Peter Murchie which the reviewer refers to, we chose not to include it in our paper as it focuses on melanoma care. In this trial we merely address basal cell carcinoma care, which we believe is quite different from melanoma care.*

5. c) there's an interesting nugget on the bottom of p11, which I think the authors should discuss. It seems that more total BCCs were removed in the intervention group (54, of which 40 were removed by the 58 GPs) than the control arm (29, from 70 GPs). Now this IS interesting. Has the intervention had a diagnostic effect? Or, if not diagnostic (as we know the number of excised BCCs was very small to the number diagnosed, but don't know if it differs across arms) has there been a treatment effect? It looks as if you are twice as likely to have a BCC removed if the GP can do it.

*The reviewer indeed highlights a very interesting issue, which we will discuss in a related paper (Noels et al, Short training improves diagnostic skin cancer skills of general practitioners; a multi-centre cluster RCT. Submitted for publication).*

## Reviewer: 2

Thank you for inviting me to review this mixed methods process evaluation of a randomized trial of substituting surgical excision of low risk BCC from secondary to primary care. The authors describe the "SKINCATCH" trial, a multi-centre cluster randomized non-inferiority trial. GPs were trained in BCC and skin tumour management with a view to excising low risk BCCs in primary care. The trial evaluated completeness of excision, diagnostic accuracy, patient reported outcomes, and cost-effectiveness. I had to read the paper through a few times to understand exactly what was being reported here, and what would be reported elsewhere. The main trial results will presumably be reported elsewhere, and the important process evaluation of experiences/views about shifting care towards the community have also been reported elsewhere. My understanding is that this paper reports: GP experiences of the training and trial participation; specific barriers to the inclusion of patients (telephonic interview); GPs experiences of participating in the trial (focus groups); and number of potentially eligible patients/excisions over the trial period (medical record review). There were some very specific findings about low patient volume during the study period, problems with trial organisation, clarity of case report forms, administrative challenges, etc. I struggled to pick out the more generalisable learning points from this paper. I have made some more specific comments below:

1. The paper has very long methods and results sections, which made it more difficult to pick out the key messages. Perhaps a difficulty that the authors have faced is in trying to describe the trial itself in this paper, its design, outcome measures, power calculations, etc. whilst also distilling the main aims/methods of this process evaluation. It would help to be able to reference a trial protocol if one has been published, or the report of the trial itself (is the process evaluation being published before the main trial results)? There is one reference to a report of another process evaluation – qualitative interviews in which clinicians have given their views about substituting hospital care with primary care.

*We understand the reviewer's comment regarding the long methods and results section in which we describe both the trial itself and the process evaluation. Unfortunately we do not have a trial protocol to refer to. In the absence of this, we have tried to make a clearer distinction between the Description*



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*of the SKINCATCH trial (p. 5-7) and Design and Data collection, outcome measures and analyses of the process evaluation (p. 8-10).*

2. Abstract and main paper: Is the low inclusion rate of low risk BCCs a finding of this process evaluation or of the trial itself (which then informed the process evaluation)? Line 134: "For this process evaluation, we focussed only on the low inclusion rate of low-risk BCC by GPs rather than all skin lesions suspicious for cutaneous malignancies, which made it impossible to measure the primary outcome". This sentence wasn't very clear to me, but it seems that the process evaluation was based around/informed by the fact that few low risk BCCs were excised/included by GPs in the trial. This result is not presented up front in this paper – it is presented as a result of the process evaluation.

*The process evaluation was indeed informed by the fact that few low risk BCCs were included by GPs in the trial. To clarify this, we have rephrased the particular sentence. (p7, line 135-137)*

3. Abstract: Interesting results about barriers (low patient volume, patients requesting referral) are listed in the conclusions section rather than the results

*Results about barriers are reported both in the results section as well as in the conclusions of the abstract.*

4. Background: I think there are a few typographical errors: "being low complex care"; "patient inclusion rate was somewhat conform expectations".

*We thank the reviewer for pointing this out and have addressed these typographical errors in the manuscript. (p4, line75; p5 line 91-92)*

5. Methods: Is current standard of care a method or does it belong in the background section?

*We agree with the reviewer this information belongs to the background section. We have replaced this accordingly.*

Similarly and as mentioned above, the results of the SKINCATCH trial are not presented in this paper, but much of the methods section covers trial methodology.

*Indeed, the main results of the SKINCATCH trial are not presented in this paper. As we do not have a trial protocol paper to refer to and we believe some basic information on the SKINCCATCH trial is necessary to understand this process evaluation, we have now tried to make a clearer distinction between the Description of the SKINCATCH trial and the Design and Data collection, outcome measures and analyses of the process evaluation.*

6. Section: "Server analysis": I wasn't clear about what a server analysis was. Is the server a computer server and is "server analysis" an analysis of data from a computer server?

*With 'server analysis' we actually mean an analysis of the database. We have adjusted this throughout the manuscript.*

## Reviewer: 3

Thank you for the opportunity to review this manuscript. This study addresses two topics that are highly relevant to healthcare systems in various jurisdictions: (1) the "substitution" of services from specialist to primary care as a means of increasing system capacity and promoting system



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sustainability, and (2) understanding how and why healthcare interventions do or do not result in the desired outcomes. Please see my specific comments below. Many are relatively minor suggestions to improve clarity; however, I have also suggested a number of areas where additional detail would strengthen the manuscript.

1. Title: -Consider rewording the title to explicitly state that this is process evaluation.

*We thank the reviewer for his useful comment and have changed the title to explicitly state it is a process evaluation (see also Reviewer 1, comment 1).*

2. Strengths and Limitations: Line 26: The second bullet (line 26) states "It provides essential in-depth insight into the general practitioners' exposure to the intervention as well as their implementation and experiences with the trial". In this sentence it is unclear what "their implementation" is referring to (i.e., their implementation of what?). Consider revising this sentence as follows: "It provides essential in-depth insight into the general practitioners' exposure to the intervention, implementation of the intervention, and experiences with the intervention and trial."

*We agree with the reviewer and have adopted the reviewers' suggestion to improve this sentence. (p.2, line 26-27)*

3. Abstract:
    a. Line 37: Consider restating the aim as "…to investigate GPs' exposure to the intervention, implementation of the intervention, and experiences with the intervention and trial." This is consistent with the results section which presents GPs' experiences with both the intervention and the trial.

*We agree with the reviewer and have adopted the reviewers' suggestion to improve this sentence. (p.2, line 36)*

    b. Line 37-38: In the conclusion of the abstract it mentions training, but up until that point it is not clear what intervention the GPs were exposed to. Perhaps after sentence 2, a sentence could be added explaining that one group of GPs received an educational intervention.

*We agree with the reviewer and have adopted the reviewers' suggestion to clarify this issue. (p.2, line 34-35)*

    c. Line 41: Replace "record analyses" with "medical record analyses"

*We have replaced the words as suggested by the reviewer. (p.2, line 40)*

    d. Line 42: Consider using the term "focus groups" instead "focus group meetings" throughout the manuscript.

*We have replaced the term 'focus group meetings' with 'focus groups' throughout the manuscript.*

    e. Related to methods, server analysis is not mentioned in the abstract.



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*In order to comply with the abstract word limit we only mentioned that the paper consists of complementary quantitative and qualitative components. Following the reviewer's suggestion, we have now added this information to the abstract. (p. 2 line 39-40)*

f. Lines 43-44: The authors state that "qualitative data were summarized or audio-recorded, transcribed verbatim and thematically analysed using Atlas.Ti." Does "summarized" mean that mean that in some cases, the researcher took notes summarizing what the participant said rather than audio-recoding? If so, it would be helpful to be explicit, and also to indicate in the methods section how many individuals were audio-recorded in total.

*The focus groups were audio-recorded and transcribed verbatim, whereas the telephonic barrier interviews were not audio-recorded but summarized by one of the authors. We have now clarified this in abstract (p2 line 42-43).*

g. Line 47: What does the denominator refer to? Are these suspicious cutaneous lesions? Or confirmed low-risk BCCs? Here, it reads as if only 56 of 316 BCCs were treated by GPs in the intervention arm. If this is the case, please clarify.

*We apologize for the unclarity. The nominator is the number of low-risk BCCs included; the denominator is the number of all skin tumours included (this may be for example a high-risk BCC, or other type of skin cancer/tumour). (p.2 line 46)*

h. Line 54: How are inclusion rate and excision rate different? This is not immediately clear, however, additional details around patient identification/recruitment in the manuscript may help make this more obvious.

*We agree with the reviewer. However, as a result of the word limit of the abstract we could not provide additional details in the abstract, but have included this information in the methods section.*

4. Background:
   a. Line 71: Consider replacing "healthcare domain" with "type of care". Healthcare domain seems like too broad of a term. Using "type of care" also aligns with the wording used in the previous sentence (i.e., "not every type of care may be suitable…"

*We have replaced this accordingly. (p. 4, line 71)*

b. Line 75: Similar to my previous comment, consider replacing "One of the healthcare domains conceived as…" with "One type of care that has been conceived as…"

*We have replaced this accordingly. (p. 4, line 75)*

c. Line 83: This is the first mention of the SKINCATCH Trial. Although a detailed description is provided further down, the way this paragraph is currently written seems to assume that the reader is already familiar with the trial. Including a brief descriptive sentence, or two, would be helpful in understanding the context for this manuscript.



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*We have added the suggested additional information. (p.3, line 88-90)*

d. Lines 85-87: The following sentence is unclear: "although the patient inclusion rate was somewhat conform expectations for all skin lesions suspicious for a cutaneous malignancy, the inclusion rate of low-risk BCCs (primary outcome) lagged far behind." Please revise for clarity. In doing so, please consider replacing the word "conform" with "conformed to" or "consistent with".

*We have adjusted this accordingly. (p.4 line 92)*

e. Line 91-93: As suggested previously, considering changing the wording of the aim from "to assess GPs' exposure to the intervention, as well as their implementation and experiences with the SKINCATCH Trial" to "to assess GPs' exposure to the intervention, implementation of the intervention, and experiences with the intervention and SKINCATCH Trial."

*We have adjusted this accordingly. (p.4 line 98-99)*

5. Methods:
   a. The information about the current standard of care seems out of place in the methods section. I suggest incorporating this information into the background section of the manuscript.

*We agree with the reviewer that the current standard of care belongs to the Background section of the manuscript rather than the methods and have adjusted this accordingly (p.4 line 76-83)*

b. It would be helpful if the authors provided a logic model (in table form would be sufficient) to show the data collection activities being carried out as part of the process evaluation, the specific information obtained from each data collection activity, and how this relates to the objectives/outcomes of interest.

*We would like to refer to table 2.*

c. In various places throughout the manuscript the terms skin cancer, skin tumour, skin lesion, and cutaneous malignancy are used. If these terms are being used interchangeably, please select the appropriate term(s) for consistent use throughout.

*We have unified the terminology throughout the manuscript.*

6. Design SKINCATCH Trial:
   a. The description of the trial would benefit from additional detail, particularly around implementation in the clinical setting (E.g., What were GPs asked to do exactly? How were eligible patients identified? How much contact did the research team have with the GPs throughout the trial?). Huschler et al (2003) provide a useful framework for explaining the key features of an intervention.

*We indeed used the framework of Hulscher et al (reference 18) in designing our paper. Table 1 provides an overview of the interventions, recommendations and outcome measures. Further*



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*information about the Trial can be found in the methods and results section (database analysis and server analysis).*

b. Line 108-109: Change "histological completeness rate of low-risk BCCs by GPs in the intervention group" to "histological completeness rate of low-risk BCC excisions by GPs in the intervention group compared to dermatologist".

*We have clarified this into the following: 'Main outcomes included the histological completeness rate of low-risk BCC excisions by GPs in the intervention group compared dermatologists (primary outcome)'. (p.5 line 107-108)*

c. Line 112: The authors state that" The GPs in the intervention group were offered an extensive training in BCC (and skin tumour) management..". What training did they receive exactly? Was it broad training about skin tumours with a focus on BCCs? Please clarify.

*We understand the reviewer's comment and have clarified this in description of the SKINCATCH trial (p 6 line 112-114) and also in table 1.*

d. Line 114: My understanding is that the care-as-usual group did not receive the 2-day educational intervention. If that is correct, please replace "did not receive additional training regarding the management of skin cancer" with "did not receive the 2-day educational intervention."

*We have adjusted the text as suggested. (p. 6 line 114-115)*

e. Table 1: Currently, the outcomes appear in the table in the first 4 rows. Consider presenting interventions, followed by recommendations, followed by outcome measures. This would be consistent with the table title and would improve flow.

*We have adjusted this accordingly. (table 1)*

7. Data collection, outcome measures, and analyses
   a. Line 134: The authors state, "For this process evaluation, we focussed only on the low inclusion rate of low-risk BCC by GPs rather than all skin lesions suspicious for cutaneous malignancies, which made it impossible to measure the primary outcome." This is confusing seeing as the primary outcomes was histological completeness rate, specifically for low-risk BCCs. Could the authors please clarify this statement.

*Please see reviewer 2 comment 2 for our response.*

b. Line 136: Please provide additional details about the evaluation framework. Is there a reason why this particular framework was used?

*The framework of Hulscher et al is a well-known framework for process evaluations. This framework differentiates between the actual exposure to the intervention and the experiences with the intervention and trial and as such is a well suitable framework for this particular trial and process evaluation.*



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c. Line 137: Change “insight in” to “insight into”.

*We have adjusted this accordingly. (p. 7 line 145)*

d. Lines 137-137: What is the difference between mechanism and process in the context of this study?

*We agree with the reviewer that these terms are more or less the same and have therefore rephrased the particular sentence. (p. 7 line 146)*

e. Lines 138-140: Change “Besides from describing the intervention, data on exposure to the intervention, and implementation of and experiences with the trial were obtained “ to “Data on exposure to the intervention, implementation of the intervention, and experiences with the intervention and trial were obtained.”

*We have adjusted this accordingly. (p. 7 line 146-149)*

8. Ethics, consent and permissions
   a. Was the process evaluation approved as part as the research ethics approval for the trial?

*As the low inclusion rate of BCCs was the reason to perform this process evaluation it was not part of the original ethics approval for the trial. However, participation was on a voluntary basis and informed consent was obtained from each participant.*

b. Was consent obtained only from GPs participating in the study, or was consent also obtained from patients who were included in the trial? When was consent obtained from the relevant groups?

*Consent was obtained from both participating GPs as well as participating patients, prior to inclusion to the trial. In addition, we obtained consent from participating GPs for the qualitative components of the process evaluation.*

c. Line 146: Many elements of the SRQR guidelines have not been addressed in the manuscript. For example, sampling strategy, research paradigm, citations for analytic approach.

*The SRQR guideline was added to conform to the journals requirements for qualitative studies. However, since this is a process evaluation consisting of both quantitative and qualitative components rather than qualitative components alone, some elements are not applicable. We have added this information to the manuscript. (p 7 line 142-143)*

9. Surveys
   a. Line 148: Change “during the course of trial” to “during the course of the trial”.

*We have adjusted this accordingly. (p. 8 line 153)*

b. Line 148-149: Change “to assess their exposure and their experiences with the trial” to “to assess their exposure to the intervention and their experiences with the



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intervention and trial". The results address experiences with both the intervention and the trial, so this should be reflected in the wording used elsewhere.

*We have adjusted this accordingly. (p. 8 line 154)*

c. The authors indicate that the 2 surveys are included as Appendix A and Appendix B. Is this correct? The submission did not contain appendices, however, the training evaluation survey appears as Figure 2 with additional information contained in a supplement.

*We apologize for the inconvenience.*

d. Line 153: Although a Likert scale is being used, experiences cannot really be "measured" quantitatively. Consider replacing with "were measured" with "were assessed".

*We have adjusted this accordingly. (p. 8 line 159)*

10. Server analysis
    a. I am not familiar with "server analysis". Might this be considered a "database analysis" (i.e., of the OpenClinica database)?

*We have replaced the term server analysis with database analysis.*

b. Line 162: Replace "insight in" with "insight into"

*We have adjusted this accordingly. (p. 8 line 168)*

c. Line 164: After "inclusions for the primary outcome measure of the trial" it would be helpful to add "histological completeness" in parentheses.

*We have added this suggestion. (p. 8 line 170-171).*

d. The data contained in the CRF are briefly explained, but which data elements variables were analysed for the process evaluation and which descriptive statistics were calculated.

*Descriptive statistics were used to assess the number of performed low-risk BCC excisions as compared to the number of included low-risk BCCs. (p 9 line 175-176)*

11. Medical record analysis: This component included only 7 GPs from two practices. This represents a very small sample of the total number of physicians and practices enrolled in the trial. How were these GPs and practices selected? How does this activity contribute to the overall evaluation? The justification/benefit of this activity could be made clearer.

*These 7 GPS were randomly selected. This information is added to the manuscript (p 9, line 198). This analysis was done to obtain quantitative information on overall eligible patients. As we observed low inclusion rate of low-risk BCCs in the database analysis, two reasons could have caused this: (1) low volume of low-risk BCC in the population, or (2) low inclusion rate by the GP. The medical record*



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*analysis showed that the volume of low-risk BCC in the population is low. Therefore we cannot 'blame' the GPS for not including them.*

12. Telephonic 'barrier' interview
    a. Lines 186-187: The authors state that "Purposive sampling was used in which both GPs with no inclusions as well as GPs with one or more inclusions of patients of both groups of the trial were invited to participate." This reads as if all GP were invited to attend (0 visits and one or more visits, and both arms). Please clarify how purposive sampling was done.

*We have clarified this in the appropriate section. (p. 9 line 193)*

    b. Line 187: Replace "groups of the trial" with "arms of the trial".

*Please see our revisions following comment 12a.*

    c. Line 189: The authors state "The survey was conducted". Please clarify whether this was an interview or a survey. In addition, it this was an interview, please indicate whether it was structured, or semistructured?

*We thank the reviewer for pointing this out and have added this information. (p 9 line 195)*

    d. Line 192: The authors state that they summarized the main barriers. Was descriptive analysis used? Thematic? Please clarify and provide appropriate references.

*We have added the requested information (p 9 line 197)*

13. Focus groups
    a. The level of detail provided in this section is excellent. The authors have made the process of conducting the focus groups very clear.

*We thank the reviewer for his/her compliment.*

    b. Line 214: Please provide an appropriate reference for constant comparison.

*We have added appropriate references as requested. (p. 10 line 219)*

14. Results:
    a. Table 2: It is not always clear which denominator is used in calculating percentages which may create confusion.

*We have added the denominator in the column head.*

    b. Did GPs in the non-intervention arm have access to the online training module, or was this only available to the GPs in the intervention arm?

*Only GPs in the intervention arm had access to the online training module. This is further clarified in Table 1.*

15. Implementation of the trial: Paragraph 1: What does it mean that 600 patients were included? Does this mean that 600 patients with suspicious cutaneous lesions presented to



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the GPs enrolled in the study? Or that 600 enrolled in the study? Additional details earlier on in the manuscript about patient identification and recruitment would be beneficial.

*A total of 600 patients with a suspicious skin tumour were included in the trial. We have now included this information earlier on in the manuscript (p 7 line 133).*

16. Experiences with the intervention and trial
    a. Lines 251 and 260: Consider replacing the word "stated" with "indicated".

*This was replaced throughout the manuscript.*

    b. Line 263-266: What instruction was given to GPs in the care-as-usual arm? Perhaps this could be made clear earlier on in the manuscript when explaining the trial.

*This is clarified in description of the Skincatch trial (p 6 line 114-115). The GPs in the care-as-usual group did not receive additional training regarding the management of skin cancer the 2-day educational intervention and where asked to provide skin cancer care the way they were used to.*

    c. Line 273: What does "having to treat the patient differently" mean?

*By this we mean different from what they were used to. We have clarified this in the manuscript. (p 13 line 281)*

    d. Line 280: Change "GPs indicated to expect" to "GPs indicated that they expected" or "GPs expected".

*We have adjusted this accordingly. (p 14 line 288)*

    e. Line 282: What process was considered too time consuming? E.g. patient identification and/or recruitment, the surgical procedure itself?

*GPs found doing the informed consent procedure and filling in several forms time consuming. We have clarified this in the manuscript. (p14 line 298).*

    f. Line 282: Consider replacing "the information given during the training having subsided" with "difficulty retaining information over time".

*We have adjusted this accordingly. (p. 14 line 290-291)*

    g. Line 289: The "elaborate inclusion procedure" should be described earlier on in the manuscript, when the trial is being explained.

*We have clarified this in the manuscript.*

    h. Line 291: Replace "GPs stated to lack suggestions" with "GPs lacked suggestions".

*We have adjusted this accordingly. (p 14 line 300)*

    i. Line 292: Replace "reported to have experienced the start of the trial as" with "reported that the start of the trial was".



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*Although we understand the reviewer's comment we have not adjusted this, as we believe that reporting it as an experience is rather different from stating it factually.*

j. Lines 300-301: Replace "included researchers to collect the data themselves" with "included having researchers collect the data themselves".

*We have adjusted this accordingly. (p 15, line 309)*

k. Line 313: Patient questionnaires are mentioned here for the first time. It would be helpful if this information appeared earlier on in a description of the trial.

*This information is added to the methods section. (p. 6 line 119)*

l. Lines 316-318: Consider replacing "others were rather surprised hearing this and could not identify themselves with this statement" with something along the lines of "others were rather surprised hearing this as it did not align with their own experiences".

*We have adjusted this accordingly. (p 15 line 327-328)*

17. Discussion:
    a. In implementation science, integrated knowledge translation to help ensure that relevant stakeholders groups have input into the identification of research priorities, study design, intervention design and implementation, etc. To what extent were relevant stakeholder groups involved in this study? The authors note that a barrier analysis at the outset would have been beneficial, however, an integrated knowledge translation approach may have mitigated some of the barriers that arose (e.g., administrative issues, clarity of forms, alignment between trial design and clinical practice, etc.). Can the authors comment on this?

*We agree it is important to involve stakeholder groups when designing a comprehensive trial such as the one presented here. Both GPs and dermatologists were included in the design of the study. However, a thorough barrier analysis before the onset of the trial was not performed.*

b. Line 324: The authors state that "participation in the highly valued training was optimal." On what basis is this statement made? That is, why do the authors consider participation to have been optimal?

*This statement is based on the fact that all GPs (the maximum number) participated in the (highly-valued) training, which is the result of the training evaluation survey, presented on page 12 of the manuscript.*

c. Line 341: Replace "Besides from the low volume" with "Aside from the low volume".

*This was adjusted accordingly. (p. 16, line 351)*

d. Line 342: "the number of excisions performed by GPs in the intervention group was much lower than possible". What do the authors mean by "much lower than possible"?



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*We mean that more patients were eligible for excision and have adjusted the text accordingly.*

e. Line 345: The authors state, "Also, patients requesting a referral to a dermatologist was reported as a barrier to perform excisions themselves." Please revise this sentence to clearly reflect that the word "themselves" refers to GPs. Also, this statement is a finding of the current study, but it is followed by a number of references to the literature. Is this intended to show that the statement is consistent with what has been reported elsewhere? Please clarify the relationship between the statement and the cited literature.

*We have rephrased this sentence for clarification. (p 16, line 353-355)*

f. The lack of data for the e-leaning module should be acknowledged as a limitation, as well as the small *n* for the medical record analysis.

*We have added these limitations to the manuscript. (p18 line 381-382)*

18. Figure 1: The figure doesn't capture the e-learning module.

*As we were unable to measure the use of the e-learning module and this was reported to vary substantially within the intervention group, we did not capture this as an element of the intervention in the figure.*

FORMATTING AMENDMENTS (if any)
Required amendments will be listed here; please include these changes in your revised version:
• Figure/s should be in better quality
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*As requested we have improved the quality of the figure.*

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# Process evaluation of a multi-centre randomized clinical trial of substituting surgical excisions of low-risk basal cell carcinomas from secondary to primary care

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# Process evaluation of a multi-centre randomized clinical trial of substituting surgical excisions of low-risk basal cell carcinomas from secondary to primary care

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## Article Summary – Strengths and limitations of this study

- This process evaluation uses complementary descriptive quantitative measures and qualitative measures at different time points during the course of the trial.
- It provides essential in-depth insight into general practitioners' exposure to the intervention, implementation of the intervention, and their experiences with the intervention and trial.
- Future trials may benefit from thorough qualitative barrier analysis among all involved stakeholders before the onset as well as during the course of the trial.


## Abstract

**Objectives**

In 2016 the SKINCATCH Trial, a clustered multi-centre randomized trial, was initiated to assess whether low-risk basal cell carcinomas (BCCs) can be treated by general practitioners (GPs) without loss of quality of care. The trial intervention consisted of a tailored 2-day educational course on skin cancer management. The aim of this process evaluation was to investigate GPs' exposure to the intervention, implementation of the intervention, and experiences with the intervention and trial.

**Research design and methods**

Data on exposure to the intervention, implementation and experiences was obtained at several points during the trial. Complementary quantitative components (i.e. surveys, database analysis, medical record analysis) and qualitative components (i.e. interviews and focus groups) were used. Quantitative data were analysed using descriptive statistics; qualitative data were summarized (barrier interviews) or audio-recorded, transcribed verbatim and thematically analysed using Atlas.Ti (focus groups).

**Results**




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Following a 100% intervention *exposure*, results concerning the *implementation* of the trial showed that aside from the low inclusion rate of patients with low-risk BCCs (n=54), even less excisions of low-risk BCCs were performed (n=40). Although the intervention was *experienced* as highly positive, several barriers were mentioned regarding the trial including administrative challenges, lack of time and high workload of GPs, low volume of BCC patients and patients declining to participate or requesting a referral to a dermatologist.

**Conclusions**

Although GPs' participation in the highly valued training was optimal, several barriers may have contributed to the low inclusion and excision rate of low-risk BCCs. While some of the issues were trial-related, other barriers such as low patient-volume and patients requesting referrals are applicable outside the trial setting as well. This may question the feasibility of substitution of surgical excisions of low-risks BCCs from secondary to primary care in the current Dutch setting.

**Trial registration number**: Trial NL5631 (NTR5746)

## Key words (3-10)

Skin cancer, basal cell carcinoma, dermatology, primary care, general practitioner, substitution of care

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## Background

Health care is becoming increasingly expensive with rising percentages of the gross domestic product spent on health care.[1-3] Since research has shown health systems with stronger primary care tend to have lower health care costs, initiatives such as substitution of hospital care towards primary care are increasingly developed and experimented with worldwide.[4-13] The main goal of these initiatives is to maintain the affordability, and thus sustainability, of healthcare. Furthermore, it is a means to provide more easily accessible care closer to the patients' home. However, not every type of care may be suitable for substitution towards primary care. Whether a particular type of care is deemed appropriate for substitution depends on various disease and care specific factors, such as high-volume and being low-complex care, and the support of different stakeholders including general practitioners (GPs), medical specialists, and patients.[5]

One type of care that has been conceived as a potential candidate for substitution of hospital care towards primary care is low-risk skin cancer care.[5 14] In the Netherlands, as in several other countries such as the UK and Australia, GPs have a gatekeeper function.[5 15 16] Consultations are mainly patient driven, and GPs, who until recently did not have a related primary care guideline, determine whether patients need access to secondary and tertiary healthcare.[17] A substantial proportion of patients with a BCC (60% in a comprehensive Dutch primary care database analysis) are referred to the dermatologist.[18-21] The idea of substituting low-risk skin cancer care to GPs is reflected in the recently published guideline 'suspicious cutaneous lesions' of the Dutch College of General Practitioners, which includes recommendations for GPs on the diagnosis and treatment of low-risk BCCs.[17] Particularly, low-risk basal cell carcinomas (BCCs) (i.e., non-aggressive histological subtypes, low-risk locations and size <2 cm) are relatively easy to diagnose and treat. Minor surgery can be performed in primary care offices, and innovations such as teledermatology can support GPs.[22 23]

In 2016 the SKINCATCH Trial (SKIN Cancer And Tumour Health Care) was initiated to assess whether low-risk BCCs can be treated by GPs without loss of quality of care. The study design was a multi-



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centre cluster randomized non-inferiority trial, in which the intervention included a tailored 2-day educational course on skin cancer management. Participating GPs showed great enthusiasm and interest at the start of the trial [14], and although the patient inclusion rate of all skin tumours suspicious for skin cancer was consistent with the researchers' expectations, the inclusion rate of low-risk BCCs (primary outcome) lagged far behind.

Therefore, a process evaluation was conducted alongside the trial. A process evaluation is crucial for providing insight in to what extent the trial intervention was actually implemented, how it was experienced by study participants and whether the intervention is feasible in daily practice.[24 25] The results can be used to guide the implementation of similar care substitution initiatives.[24] The aim of our process evaluation was, therefore, to assess GPs' exposure to the intervention, implementation of the intervention, and experiences with the intervention and trial.

## Methods

### *Description of SKINCATCH Trial*

The SKINCATCH Trial (see Figure 1) was initiated based on the hypothesis that conventional excision of low-risk BCC could be performed by GPs in a primary care setting while maintaining the same quality of care. The study design was a multi-centre cluster randomized non-inferiority trial, with GP practices (including group practices) being included as clusters. These clusters were randomized into two parallel arms: the intervention group, which was trained before starting the trial, and the care-as-usual group. Main outcomes included the histological completeness rate of low-risk BCC excisions by GPs in the intervention group compared to dermatologist (primary outcome), diagnostic accuracy of GPs regarding skin tumours, cost-effectiveness of the intervention and treatment and patient reported outcomes regarding preferences and cosmetics (secondary outcomes) (see Table 1).

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The GPs in the intervention group were offered an extensive training in BCC (and skin tumour) management consisting of a tailored 2-day educational course including hands-on surgical training in cadaveric workshops. The GPs in the care-as-usual group did not receive the 2-day educational intervention and were asked to provide skin cancer care the way they were used to. As compensation, they were offered the same BCC management training after completion of the trial. Eligible patients (i.e., all patients with a skin tumour suspicious for malignancy) were to be included in the trial during the period February 2016 to May 2018. Included patients were asked to complete questionnaires at start of their treatment, and 3 and 6 months post-treatment.

**Figure 1: Overview of SKINCATCH Trial design.**

*Abbreviations: BCC, basal cell carcinoma; CEA, cost-effectiveness analysis; GP, general practitioner; PROMs, patient reported outcome measures.*

The power analysis for the primary outcome was based on a t-test of the proportion of histological completeness of the physicians (GPs and dermatologists), where the physician is the unit of analysis. We expected 5 eligible patients in the non-inferiority part of the trial per GP per year, which was based on national incidence rates and a prior GP survey.[26 27] Using a non-inferiority margin of 5% (based on a clinically accepted margin) and a one-sided significance level of 2.5%[28], a sample size of 45 GPs per group (90 GPs total) was required to obtain a power of 80%. This sample size was increased to 129 GPs to account for (1) the possibility of drop-outs of GPs, and (2) the effect of within-practice correlations of the GPs.

**Table 1: Interventions, recommendations and outcome measures of the SKINCATCH Trial.**

| | |
|---|---|
| Main components of interventions for intervention group | A tailored 2-day educational course regarding the diagnosis and management of skin cancer with a focus on BCCs including hands-on surgical training (cadaveric workshops) |
| | An interactive 20 minute e-learning for GPs, which was available at all times during the trial |
| Main recommendations for low-risk BCC care to be performed by GPs in intervention group | When a skin tumour is suspicious for a malignancy, a biopsy should be performed |
| | If the histopathological examination confirms a low-risk BCC, the GP should perform the excision with adequate margins |



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| | |
|---|---|
| | If the histopathological examination shows a high-risk BCC or other type of skin cancer, the GP should refer the patient to the dermatologist |
| Main outcome measures | Histopathological completeness rate of low-risk BCC excisions by GPs in the intervention group compared to dermatologists |
| | Diagnostic accuracy of skin tumours |
| | Patient reported outcome measures concerning preferences on treating physician and cosmetic results of the received treatment |
| | Cost-Effectiveness Analysis |

*Abbreviations: BCC, basal cell carcinoma; GP, general practitioner.*

A total of 600 patients with a suspicious skin tumour were included in the trial; 316 patients were included by the GPs in the intervention group and contained 54 patients with a low-risk BCC (9% of the needed sample size for sufficient statistical power [n=600]). As recruitment of removed BCCs was so low, we are unable to report on the primary outcome of the trial (histological completeness rate of low-risk BCC excisions by GPs in the intervention group compared to dermatologists). The process evaluation presented in this paper was based on this low inclusion rate of low-risk BCCs.

**Ethics, consent and permissions**

Ethical approval for the SKINCATCH trial study was granted by the medical ethics committee of the Erasmus University Medical Centre in Rotterdam (MEC-2015-492). All participants have provided written informed consent. As this process evaluation is an evaluation among trial participants, conducted as integral part of the trial, we did not obtain separate ethical approval, except for the focus groups. The SRQR guidelines were applied, as far as applicable. These guidelines provide a tool for the transparent reporting of qualitative studies.[29]

## *Design process evaluation*

In designing this process evaluation we used the framework of Hulscher et al.[24] to gain insight into the processes responsible for the (variation in) results in the target group. Data on exposure to the intervention, implementation of the intervention, and experiences with the intervention and trial were obtained. We used both quantitative and qualitative components, which are described in detail below.



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## *Data collection, outcome measures and analyses*

**Surveys**

Two types of surveys were conducted among participating GPs during the course of the trial to assess their *exposure* to the intervention and their *experiences with the intervention and trial*: a training evaluation survey and an online trial evaluation survey. Participation in each of the surveys was voluntary.

Training evaluation survey – After completing the pre-study training all GPs were asked to complete a survey to evaluate the training. With this survey, both their *exposure to and experiences with the training* were assessed. The survey consisted of 8 statements (7 statements on the content of the training, and 1 statement on the organisation of the training) using a five-point Likert-scale ranging from *strongly disagree* to *strongly agree* (Appendix A).

Trial evaluation survey – Ten months after the start of the trial, an online survey was sent to all participating GPs to further explore their *experiences with the trial*. The survey consisted of 4 multiple-choice questions, focussing on experiences with the trial and assessing the perceived barriers (Appendix B).

Training and trial evaluation surveys were analysed separately using SPSS 24.0 statistical software.

**Database analysis**

To gain insight into *the implementation of the intervention* and more specifically the low inclusion rate of BCC patients, a database analysis at the end of the inclusion period was performed investigating the number of inclusions for the primary outcome measure of the trial (i.e. histological completeness of low-risk BCC excisions) based on the paper or digital case report forms (CRF)(i.e., OpenClinica).[30] The CRF included (among others) information on tumour characteristics (e.g., size and location), the histopathological diagnosis of the skin tumour and whether or not the GP performed a



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surgical excision. The CRFs in OpenClinica were exported to and analysed with SPSS 24.0 statistical software. Descriptive statistics were used to assess the number of performed low-risk BCC surgical excisions as compared to the number of included low-risk BCCs.

**Medical record analysis**

A medical record analysis was performed to further explore the *implementation of the intervention* by obtaining quantitative information regarding the number of potential eligible patients and potential eligible excisions. This analysis was performed among 7 randomly selected GPs in two primary care practices, participating in the intervention group of the trial. All GP records from February 2016 to February 2017 were screened for eligible patients by a GP practice healthcare assistant using International Classification of Primary Care (ICPC) codes for skin tumours (Appendix C). Information was obtained on number of patients, clinical diagnosis of the GP, size of the tumour, localisation of the tumour, and choice of treatment. In case of histopathological examination additional information was obtained on histopathological diagnosis from the biopsy and/or excision, and histological completeness in case of surgical excision. If the patient was referred to secondary care information was obtained on clinical or histopathological diagnosis. Descriptive statistics were used to assess the GPs' management of eligible patients.

**Telephonic 'barrier' interview**

Six months after the initiation of the trial, telephonic interviews were conducted by one of the researchers (EN) to identify GPs' *experiences with the trial* in terms of perceived barriers regarding the inclusion of patients. We invited GPs from both arms either with no inclusions or one or more inclusions to participate. After 12 interviews with GPs in the intervention group and 10 GPs in the care-as-usual group no new barriers emerged. The semi-structured interviews were conducted between August and November 2016. The data was analysed by the researcher conducting the telephonic interview (EN), noting reported elements during the interview and descriptively summarizing the main barriers afterwards.



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## Focus groups

Three focus groups were conducted between December 2017 and March 2018 to gain an in-depth understanding of GPs' *experiences with the intervention and the trial*. Focus groups were chosen as these facilitate interaction between participants, enabling us to identify the GPs' views on substitution of care, and their experiences with the trial.[31-33] All GPs participating in the trial were invited by email, containing an information leaflet about the qualitative evaluation study. GPs could register for one of the three organized focus groups by contacting one of the researchers.

The sessions were moderated by an experienced independent qualitative researcher (ML) and an assistant, both not being involved in the trial. One of the SKINCATCH Trial researchers (EN) was present during the focus groups, but only to answer substantive questions regarding the trial.

In each focus group, the discussion was semi-structured using a predefined topic list consisting of two separate parts: general views on substitution of care (part 1) and GPs' experiences with the trial (part 2). The current study focusses on the latter part (Appendix D). Results on their general views on substitution of care have been described elsewhere.[14]

All focus groups were audio-recorded with consent of participants. Subsequently, the audio tapes were transcribed verbatim and imported to Atlas.ti (version 8 for Windows) for analysis.

Two researchers (EN, ML) independently openly-coded the first transcript after which the obtained codes were discussed and a preliminary coding scheme was developed. Next, all transcripts were coded by one researcher (EN or ML) and subsequently checked by a second researcher (EN or ML). Differences were discussed and refined until agreement was reached, and new codes were added when needed. The initial coding phase was followed by the phase of constant comparison.[31] Different codes were compared and the relationship between codes were explored to detect emerging themes.



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# Results

## *Participants*

A total of 128 GPs from 90 different primary care practices were included for randomisation (Table 2). One GP in the intervention group, and 22 GPs in the care-as-usual group dropped out. Most drop outs occurred within 3 months after the start of the trial. Reported reasons mostly concerned lack of time and personal illness. All 128 GPs were included for the database analysis, and a subgroup of 7 GPs (12%) of the intervention group were included for the medical record analysis. See Table 2 for more information on the participants of the different quantitative and qualitative components. For further details regarding the focus groups see Supplementary table S1.

**Table 2: Participants (GPs) of the SKINCATCH Trial and each of the components of the process evaluation**

| *SKINCATCH Trial* | Intervention group (n=58) | Care as usual group (n=70 |
|---|---|---|
| Male, n(%) | 32 (54) | 33 (47) |
| Drop outs, n(%) | 1 (2) | 22 (31) |
| | | |
| *Quantitative components*, n(%) | | |
| Database analysis | 58 (100) | 70 (100) |
| Medical record analysis | 7 (12) | N/A |
| Training evaluation survey | 57 (98) | N/A |
| Trial evaluation survey | 24 (41) | 36 (51) |
| | | |
| *Qualitative components*, n(%) | | |
| Telephonic 'barrier' interview | 12 (21) | 10 (14) |
| Focus groups | 9 (16) | 8 (11) |
| Focus group 1 (n=8) | 4 (50) | 4 (50) |
| Focus group 2 (n=5) | 2 (40) | 3 (60) |
| Focus group 3 (n=4) | 3 (75) | 1 (25) |

*Abbreviations: GP, general practitioner*

## *Exposure to the intervention*

All GPs in the intervention group (n=58) completed the extensive 2-day training program. Regarding the e-learning, it was not possible to measure the exposure quantitatively; it could be openly accessed by GPs at all times. The focus groups suggested that a wide variation existed regarding the



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exposure to the e-learning. Whereas some GPs stated to have gone through the files, others reported not remembering it have been offered or not to have opened it due to time restrictions.

### *Implementation of the intervention*

Only 54 patients with low-risk BCC (9% of needed sample size) of the total of 600 patients with suspicious skin tumours were included in the trial. Furthermore, the GPs in the intervention group performed 95 surgical excisions of skin tumours in total, of which 40 concerned a low-risk BCC. In the care as usual group 29 of the 284 included patients concerned patients with histopathological confirmed low-risk BCCs.

The medical record analysis of potentially eligible BCCs patients in one year among 7 GPs resulted in 448 potential patients. After manual extraction by two of the authors (EN, KR), 35 confirmed BCC patients remained of which 16 were low-risk BCC. Three BCCs (19%) were excised by two of the seven GPs; the remaining 13 tumours were not excised by the GP. Reported reasons in the medical records were: preference for topical treatment (n=2), patient preference for dermatologist (n=1), referral due to melanoma in differential diagnosis (n=1), coinciding melanoma (n=1), not reported in medical record (n=8).

### *Experiences with the intervention and trial*

#### ***Experiences with the intervention***

*Training evaluation survey* - The training was generally evaluated positively by the GPs (Figure 2); almost all (n=54) indicated to have found the training useful and almost all (n=53) indicated they would recommend the training among colleagues. All GPs (strongly) agreed with the statement the training would change the way they manage skin cancer, and the vast majority (n=47) confirmed that it was clear to them what was expected regarding their participation in the trial. For further details on the training evaluation survey see Supplementary figure S1.



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Figure 2: Results from the training evaluation survey.

*Focus groups* – The focus groups confirmed that the GPs were highly positive about the training. Some reported it to be the best training they have ever had. According to the GPs it offered them guidance in managing skin tumours in general, and it was particularly useful to learn techniques for minor surgery hands-on. GPs indicated to feel more empowered to extend their services regarding skin tumour management in daily practice. However, some GPs did mention that with time passing they returned to old patterns. According to the GPs, the training may not have been enough for all GPs to change their role in the management of skin tumours. Furthermore, according to some GPs the participation in the trial caused them to diminish their role in skin cancer management as they were used to performing minor surgery on high(-er) risk skin cancers (e.g., BCCs located in the face), which was restricted by the study protocol. Regarding the e-learning, the few GPs who used the e-learning were generally positive and reported it was fun to do.

***Experiences with the trial***

*Trial evaluation survey* – Reported reasons for the low number of included (BCC) patients in the trial concerned lack of time (n=34) and realizing the patients' eligibility afterwards (n=27), patients rejected participation (n=11), not understanding the different study forms (n=5), the trial restricts me on performing excisions due to trial recommendations (n=3), the GP being afraid to perform minor surgery (n=1) and having to treat the patient different from what they were used to (n=1). A smaller group of GPs (n=13) agreed with the statement that it would make it easier for them to only include patients with a low-risk BCC rather than all skin cancers, and the largest part (n=44) disagreed with the option of clustering consultation hours for skin cancer patients for GPs individually to make patient recruitment more easy.



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*Telephonic 'barrier' interview* – During the telephonic interview six barriers were identified. Main perceived barriers reported by the GPs concerned ambiguity regarding eligibility criteria of patients, and lack of clarity regarding the trials' CRFs. GPs indicated that they expected one of the researchers to visit their practices for one-on-one explanation on the forms. Further perceived barriers included the trial not being a priority, the inclusion process being too time-consuming, difficulty retaining information over time, and discouragement due to refusal of patients or skin tumours appearing high risk.

*Focus groups* –GPs' experiences regarding the trial varied. Whereas some GPs were positive about the trial and managed to include patients (up to 53), others reported rather negative experiences. Several barriers were identified which may have contributed to the relatively low inclusion rate (both in general as well as concerning low-risk BCCs). First, *administrative challenges* related to the inclusion of patients to the trial were reported as a barrier. According to the GPs, the inclusion procedure (informed consent procedure and CRF) was difficult to integrate in daily practice with several study forms needed to be completed at different times during the treatment course of the patient. GPs reported this to be difficult and too time-consuming. However, GPs lacked suggestions on how to improve these administrative challenges as they know it is crucial for data collection. Some GPs reported to have experienced the start of the trial as rather confusing; they stated study forms were not immediately present, and that both the start-date for inclusion as well as the eligibility criteria were not clear. Others were more positive and reported to have found a way of structuring it for themselves, and commented that inaccuracies were picked up well by the researchers. The online CRF application (i.e., OpenClinica) was variably received by the GPs, though it was specifically designed for the trial in an attempt to facilitate the GPs in data registration. Some GPs reported it to be not user-friendly and continued using the paper forms, while others stated it to be of great help. Suggestions on reducing the administrative challenges included having researchers collect the data themselves by visiting the GPs' practices and using an automated digital data collection programme.



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Another reported barrier related to the administrative barrier, was a perceived *lack of time and high workload* to include patients. According to the GPs, this was related to cramped consultation hours, being behind schedule, and patients presenting multiple problems during consultation with their GP in which the skin tumour was not perceived as the main issue. As a result of the lack of time and high workload, GPs were more hesitant to recruit patients as this would consume additional time.

A third barrier as reported by the GPs was the *low volume of eligible patients* seen in practice. GPs reported to only see a small number of low-risk BCC annually. Some also stated to have seen less BCC patients during the course of the trial than anticipated, for reasons not clear.

A fourth barrier reported were *patients declining or refusing to participate* in the trial. According to the GPs, some patients did not want to participate due to the difficulty and large amount of information they had to read upon participation request, and things needed from them after inclusion (i.e., questionnaires). The GPs further mentioned that especially older patients and patients less intelligent often declined to participate.

In addition to the low inclusion rate, the GPs were also asked for possible explanations for the low rate of excisions performed by GPs during the trial. Whereas some GPs indeed reported to have only performed few excisions, others were rather surprised hearing this as it did not align with their own experiences. Reported reasons for the low number of excisions were the low number of BCC patients seen in daily practice, patients requesting a referral to the dermatologist, a lack of time and high workload, having a colleague who performs all the excisions, and the training course not being sufficient to change GPs' behaviour, particularly considering the reported already high workload.

## Discussion

This evaluation study showed that, although GPs initially showed great enthusiasm towards the concept of substitution[14], and all GPs participated in the highly valued training, several barriers may have contributed to the low inclusion and excision rate of low-risk BCC patients. Some of these



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barriers seem to be attributable to the trial setting (e.g., administrative challenges, patient recruitment issues), complicating its implementation in daily practice. However, other reported barriers such as high workload, low volume of low-risk BCC patients and patients requesting a referral, apply outside the trial setting as well.

Although several trial-related barriers, such as clear study forms and inclusion criteria, should have been adequately addressed in the current trial, other practical issues such as patient recruitment challenges are commonly reported problems within (multicentre) randomised controlled trials (RCTs) and are difficult to prevent completely.[34-38] Similarly, the reported barrier of lack of time/high workload of GPs seems to be inherently related to GP practices[38-40], and may have further impeded study implementation. To tackle these barriers, targeted interventions to enhance recruitments skills of GPs may be valuable to optimize the feasibility of trial interventions in clinical medical care.[38]

In addition to the trial-related barriers, other reported barriers also apply outside the trial setting and concern the topic of substituting low-risk BCC care towards primary care. Despite high and rising incidence rates of BCCs reported in the literature[27 41], we found that only a small proportion of BCCs can be considered 'low-risk' when taking into account body site, diameter and histological subtype[41-43], which was recently confirmed by Fremlin et al.[42] Aside from the low volume, the number of excisions performed by GPs in the intervention group was even lower. According to the GPs this may have been partly related to the training being insufficient to change GPs' practices. Also, GPs were less inclined to perform a surgical excision when patients requested a referral to a dermatologists, which has been found in previous studies as well.[14 15 44-48] These barriers, related to feasibility, need to be addressed, where possible, before assessing whether low-risk BCCs can be treated by GPs without a loss of quality of care.

Indeed, with the patient volume being this low (based on the medical record analysis approximately 2 patients with low-risk BCC per GP per year), it will be challenging, if not impossible, for GPs to obtain and maintain their competencies in low-risk BCC management.[14 42] Particularly in the context



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of this low patient volume, a one-day training may not be sufficient to acquire the relevant competencies. Offering adequate training in a repetitive setting tailored to the specific needs of each GP may therefore contribute to a better integration of what is learned into daily practice.[49 50] Although this was attempted by offering an e-learning module, the uptake (although variable) seemed to be only minimal. Furthermore, the cost-effectiveness of such interventions may be questioned. Other solutions may focus on organizational changes in primary care such as concentrated substitution.[14] Within this concept GPs refer patients to a colleague GP with noted interest, experience and competence in skin cancer care, thereby clustering these patients within or between practices.[14]

A limitation of our study includes the late conduction of a barrier analysis. Implementation of change is a complex process, and a preceding barrier analysis among all involved stakeholder groups is advocated to increase the success of interventions.[51] By addressing identified barriers prior to the onset of this trial, failure may have been prevented. In addition, such input can serve to promote awareness and stimulate involvement among the target groups, incentivizing more successful adoption at a later stage.[52] However, it is also important to elicit views of stakeholders who already have some experience with the intervention at hand, as this often elicits different types of barriers.[14] Performing a barrier analysis both before the onset of the trial as well as during the trial as part of a process evaluation is therefore advised.

A strength of this study is that we used several complementary evaluation methods, combining both quantitative and qualitative data at different time points during the course of the trial, focusing on both the intervention and care-as-usual group. Although only a low number of GPs was included in the medical record analysis and data on the use of the e-learning module was lacking, by using triangulation of data we were able to capture different dimensions of the observed phenomena. As such, our process evaluation provides essential in-depth insight into the trial and the observed outcomes.



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## Conclusions

This process evaluation has identified some trial-related as well as more general topic-related barriers that may be responsible for the low inclusion and excision rate of low-risk BCC patients by GPs within the trial. Based on the results of this study, without being able to measure the surgical effectiveness of GPs, the feasibility of substituting low-risk BCC care from secondary to primary care in the current setting should be questioned. Future trials on care substitution may benefit from thorough qualitative barrier analyses among all involved stakeholders, before onset as well as during the course of the trial, to increase the likelihood of successful implementation.

**List of abbreviations**

BCC, basal cell carcinoma; CRF, case report form; GP, general practitioner; ICPC, International Classification of Primary Care.

## Declarations

### *Ethics approval and consent to participate*

Ethical approval for the SKINCATCH Trial was granted by the medical ethics committee of the Erasmus University Medical Center in Rotterdam (MEC-2015-492). All participants have provided written informed consent. As this process evaluation is an evaluation among trial participants, conducted as integral part of the trial, we did not obtain separate ethical approval except for the focus groups.

### *Consent for publication*

Not applicable.



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## Availability of data and material

The data that supports the findings of this study are available from the medical ethics committee of the Erasmus University Medical Center in Rotterdam (Contact: Interview study reference number MEC-2016-204 and Focus group study reference number MEC-2015-492), but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of the medical ethics committee of the Erasmus University Medical Center in Rotterdam.

## Patient and public involvement

This research was done without patient involvement. Patients were not invited to comment on the study design and were not consulted to develop patient relevant outcomes or interpret the results. Patients were not invited to contribute to the writing or editing of this document for readability or accuracy.

## Competing interest

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: the principal investigator received an institutional grant as financial support from Foundation Achmea Healthcare for the submitted work; no other relationships or activities that could appear to have influenced the submitted work.

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## Author contributions

EN, ML, MW, KR, RB, PB, TN involved in the concept and design of the quantitative and qualitative study. EN, ML performed the focus groups. EN, ML, KR involved in quantitative and qualitative data



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acquisition. EN, ML, MW, RB, PB, TN involved in data analysis and interpretation. The paper was written by EN and ML, and was critically revised by all authors. All authors read and approved the final manuscript.

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## References

1. Alberto M, David M, Luca L, et al. Future trends in health care expenditure. 2017 doi: doi:https://doi.org/10.1787/247995bb-en
2. OECD. Better Ways to Pay for Health Care2016.
3. Mackenbach JP. [What are the health benefits of the most expensive healthcare system in Europe?]

Wat levert de duurste gezondheidszorg van Europa ons op? *Ned Tijdschr Geneeskd* 2015;159:A9433. [published Online First: 2015/08/27]
4. de Jong J, Korevaar J, M. K, et al. Substitution potential between primary and secondary health care. www.nivel.nl: NIVEL, 2016:50.
5. Van Dijk C, Korevaar J, De Jong J, et al. Room for substitution? Shift from secondary to primary care. . NIVEL: NIVEL, 2013:109.
6. van Hoof SJ, Kroese ME, Spreeuwenberg MD, et al. Substitution of Hospital Care with Primary Care: Defining the Conditions of Primary Care Plus. *Int J Integr Care* 2016;16(1):12. doi: 10.5334/ijic.2446 [published Online First: 2016/09/13]
7. van Hoof SJ, Spreeuwenberg MD, Kroese ME, et al. Substitution of outpatient care with primary care: a feasibility study on the experiences among general practitioners, medical specialists and patients. *BMC Fam Pract* 2016;17:108. doi: 10.1186/s12875-016-0498-8

10.1186/s12875-016-0498-8 [pii] [published Online First: 2016/08/11]
8. Fortney JC, Steffick DE, Burgess JF, et al. Are Primary Care Services a Substitute or Complement for Specialty and Inpatient Services? *Health Services Research* 2005;40(5p1):1422-42. doi: doi:10.1111/j.1475-6773.2005.00424.x
9. Laurant M, Reeves D, Hermens R, et al. Substitution of doctors by nurses in primary care. *Cochrane database Syst rev* 2005;2(2):CD001271.
10. Martínez-González NA, Djalali S, Tandjung R, et al. Substitution of physicians by nurses in primary care: a systematic review and meta-analysis. *BMC Health Services Research* 2014;14(1):214. doi: 10.1186/1472-6963-14-214
11. Weller DP. Workforce substitution and primary care. *Med J Aust* 2006;185(1):8-9. doi: wel10579_fm [pii] [published Online First: 2006/07/04]
12. Yong CS. Task substitution: the view of the Australian Medical Association. *Med J Aust* 2006;185(1):27-8. doi: yon10552_fm [pii] [published Online First: 2006/07/04]



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Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

13. Starfield B, Shi L. Policy relevant determinants of health: an international perspective. *Health Policy* 2002;60(3):201-18. doi: S0168851001002081 [pii] [published Online First: 2002/04/20]
14. Noels EC, Wakkee M, Van den Bos R, et al. Substitution of low risk skin cancer hospital care towards primary care: a qualitative study on views of general practitioners and dermatologists. 2019
15. Greenfield G, Foley K, Majeed A. Rethinking primary care's gatekeeper role. *BMJ* 2016;354:i4803. [published Online First: 2016/09/25]
16. Moreno G, Tran H, Chia ALK, et al. Prospective study to assess general practitioners' dermatological diagnostic skills in a referral setting. *Australasian Journal of Dermatology* 2007;48(2):77-82. doi: doi:10.1111/j.1440-0960.2007.00340.x
17. Baaten GGG, Buis PAJ, Damen Z, et al. NHG-Standaard Verdachte Huidafwijkingen 2017 [Available from: https://www.nhg.org/standaarden/volledig/nhg-standaard-verdachte-huidafwijkingen.
18. van Dijk CE, Verheij RA, Spreeuwenberg P, et al. Minor surgery in general practice and effects on referrals to hospital care: Observational study. *BMC Health Services Research* 2011;11(1):2. doi: 10.1186/1472-6963-11-2
19. Lowell BA, Froelich CW, Federman DG, et al. Dermatology in primary care: Prevalence and patient disposition. *J Am Acad Dermatol* 2001;45(2):250-5. doi: S0190-9622(01)84392-9 [pii]

10.1067/mjd.2001.114598 [published Online First: 2001/07/21]
20. M.E. B-vD, Y.M. W, K. H, et al. Zorg door de huisarts. . *Jaarcijfers 2017 en trendcijfers 2011-2017* 2018 18-07-2018. (accessed 07-11-2018).
21. Wakkee M, Van Egmond S, Louwman M, et al. Opportunities for improving keratinocyte cancer care in primary and specialist care: a Dutch cohort study.
22. Eminovic N, Dijkgraaf MG, Berghout RM, et al. A cost minimisation analysis in teledermatology: model-based approach. *BMC Health Serv Res* 2010;10:251. doi: 1472-6963-10-251 [pii]

10.1186/1472-6963-10-251 [published Online First: 2010/08/27]
23. van der Heijden JP, de Keizer NF, Bos JD, et al. Teledermatology applied following patient selection by general practitioners in daily practice improves efficiency and quality of care at lower cost. *Br J Dermatol* 2011;165(5):1058-65. doi: 10.1111/j.1365-2133.2011.10509.x [published Online First: 2011/07/07]
24. Hulscher ME, Laurant MG, Grol RP. Process evaluation on quality improvement interventions. *Qual Saf Health Care* 2003;12(1):40-6. [published Online First: 2003/02/07]
25. Moore GF, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ : British Medical Journal* 2015;350 doi: 10.1136/bmj.h1258
26. de Vries E, Nijsten T, Louwman MW, et al. [Skin cancer epidemic in the Netherlands]

Huidkankerepidemie in Nederland. *Ned Tijdschr Geneeskd* 2009;153:A768. [published Online First: 2009/12/23]
27. Flohil SC, de Vries E, Neumann HA, et al. Incidence, prevalence and future trends of primary basal cell carcinoma in the Netherlands. *Acta Derm Venereol* 2011;91(1):24-30. doi: 10.2340/00015555-1009 [published Online First: 2011/01/26]
28. Head SJ, Kaul S, Bogers AJ, et al. Non-inferiority study design: lessons to be learned from cardiovascular trials. *Eur Heart J* 2012;33(11):1318-24. doi: ehs099 [pii]

10.1093/eurheartj/ehs099 [published Online First: 2012/05/09]
29. O'Brien BC, Harris IB, Beckman TJ, et al. Standards for reporting qualitative research: a synthesis of recommendations. *Acad Med* 2014;89(9):1245-51. doi: 10.1097/ACM.0000000000000388 [published Online First: 2014/07/01]
30. Cavelaars M, Rousseau J, Parlayan C, et al. OpenClinica. *Journal of Clinical Bioinformatics* 2015;5(1):S2. doi: 10.1186/2043-9113-5-s1-s2
31. Green J, Thorogood N. Qualitative methods for health research. 3rd revised edition ed: Sage Publications Ltd 2014:233-254.



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Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

32. Krueger RA, Casey MA. Focus groups: a practical guide for applied research.: SAGE 2000.
33. Willis K, Green J, Daly J, et al. Perils and possibilities: achieving best evidence from focus groups in public health research. *Australian and New Zealand Journal of Public Health* 2009;33(2):131-36. doi: doi:10.1111/j.1753-6405.2009.00358.x
34. McDonald AM, Knight RC, Campbell MK, et al. What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies. *Trials* 2006;7:9. doi: 1745-6215-7-9 [pii]

10.1186/1745-6215-7-9 [published Online First: 2006/04/11]
35. de Wit NJ, Quartero AO, Zuithoff AP, et al. Participation and successful patient recruitment in primary care. *J Fam Pract* 2001;50(11):976. doi: jfp_1101_09760 [pii] [published Online First: 2001/11/17]
36. van der Gaag WH, van den Berg R, Koes BW, et al. Discontinuation of a randomised controlled trial in general practice due to unsuccessful patient recruitment. *BJGP Open* 2017;1(3):bjgpopen17X101085. doi: 10.3399/bjgpopen17X101085

bjgpopen17X101085 [pii] [published Online First: 2017/10/04]
37. Bower P, Wilson S, Mathers N. Short report: how often do UK primary care trials face recruitment delays? *Fam Pract* 2007;24(6):601-3. doi: cmm051 [pii]

10.1093/fampra/cmm051 [published Online First: 2007/09/18]
38. Foster JM, Sawyer SM, Smith L, et al. Barriers and facilitators to patient recruitment to a cluster randomized controlled trial in primary care: lessons for future trials. *BMC Med Res Methodol* 2015;15:18. doi: 10.1186/s12874-015-0012-3

10.1186/s12874-015-0012-3 [pii] [published Online First: 2015/04/19]
39. Croxson CH, Ashdown HF, Hobbs FR. GPs' perceptions of workload in England: a qualitative interview study. *Br J Gen Pract* 2017;67(655):e138-e47. doi: bjgp17X688849 [pii]

10.3399/bjgp17X688849 [published Online First: 2017/01/18]
40. van den Hombergh P, Kunzi B, Elwyn G, et al. High workload and job stress are associated with lower practice performance in general practice: an observational study in 239 general practices in the Netherlands. *BMC Health Serv Res* 2009;9:118. doi: 1472-6963-9-118 [pii]

10.1186/1472-6963-9-118 [published Online First: 2009/07/17]
41. Verkouteren JAC, Ramdas KHR, Wakkee M, et al. Epidemiology of basal cell carcinoma: scholarly review. *Br J Dermatol* 2017;177(2):359-72. doi: 10.1111/bjd.15321 [published Online First: 2017/02/22]
42. Fremlin GA, Gomez P, Halpern J. Are there sufficient numbers of low-risk basal cell carcinomas to justify general practitioners (family physicians) carrying out basal cell carcinoma surgery? *Clin Exp Dermatol* 2016;41(2):138-41. doi: 10.1111/ced.12718 [published Online First: 2015/07/21]
43. Lomas A, Leonardi-Bee J, Bath-Hextall F. A systematic review of worldwide incidence of nonmelanoma skin cancer. *Br J Dermatol* 2012;166(5):1069-80. doi: 10.1111/j.1365-2133.2012.10830.x [published Online First: 2012/01/19]
44. Bath-Hextall F, Nalubega S, Evans C. The needs and experiences of patients with skin cancer: a qualitative systematic review with metasynthesis. *Br J Dermatol* 2017;177(3):666-87. doi: 10.1111/bjd.15148 [published Online First: 2016/10/25]
45. van Egmond S, Wakkee M, Droger M, et al. Needs and preferences of patients regarding basal cell carcinoma and cutaneous squamous cell carcinoma care: a qualitative focus group study. *Br J Dermatol* 2018 doi: 10.1111/bjd.16900 [published Online First: 2018/06/22]
46. Wammes JJ, Jeurissen PP, Verhoef LM, et al. Is the role as gatekeeper still feasible? A survey among Dutch general practitioners. *Fam Pract* 2014;31(5):538-44. doi: cmu046 [pii]





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10.1093/fampra/cmu046 [published Online First: 2014/08/20]
47. Westert GP, Jeurissen PPT, Assendelft WJJ. Why Dutch general practitioners do not put the squeeze on access to hospital care? *Family Practice* 2014;31(5):499-501.
48. Rotar AM, Van Den Berg MJ, Schafer W, et al. Shared decision making between patient and GP about referrals from primary care: Does gatekeeping make a difference? *PLoS One* 2018;13(6):e0198729. doi: 10.1371/journal.pone.0198729

PONE-D-17-43535 [pii] [published Online First: 2018/06/12]
49. Bluestone J, Johnson P, Fullerton J, et al. Effective in-service training design and delivery: evidence from an integrative literature review. *Human Resources for Health* 2013;11(1):51. doi: 10.1186/1478-4491-11-51
50. Lugtenberg M, Pasveer D, van der Weijden T, et al. Exposure to and experiences with a computerized decision support intervention in primary care: results from a process evaluation. *BMC Fam Pract* 2015;16:141. doi: 10.1186/s12875-015-0364-0

10.1186/s12875-015-0364-0 [pii] [published Online First: 2015/10/18]
51. Grol R, Grimshaw J. From best evidence to best practice: effective implementation of change in patients' care. *Lancet* 2003;362(9391):1225-30. doi: S0140-6736(03)14546-1 [pii]

10.1016/S0140-6736(03)14546-1 [published Online First: 2003/10/22]
52. Grol R, Wensing M. What drives change? Barriers to and incentives for achieving evidence-based practice. *Med J Aust* 2004;180(6 Suppl):S57-60. doi: gro10753_fm [pii] [published Online First: 2004/03/12]

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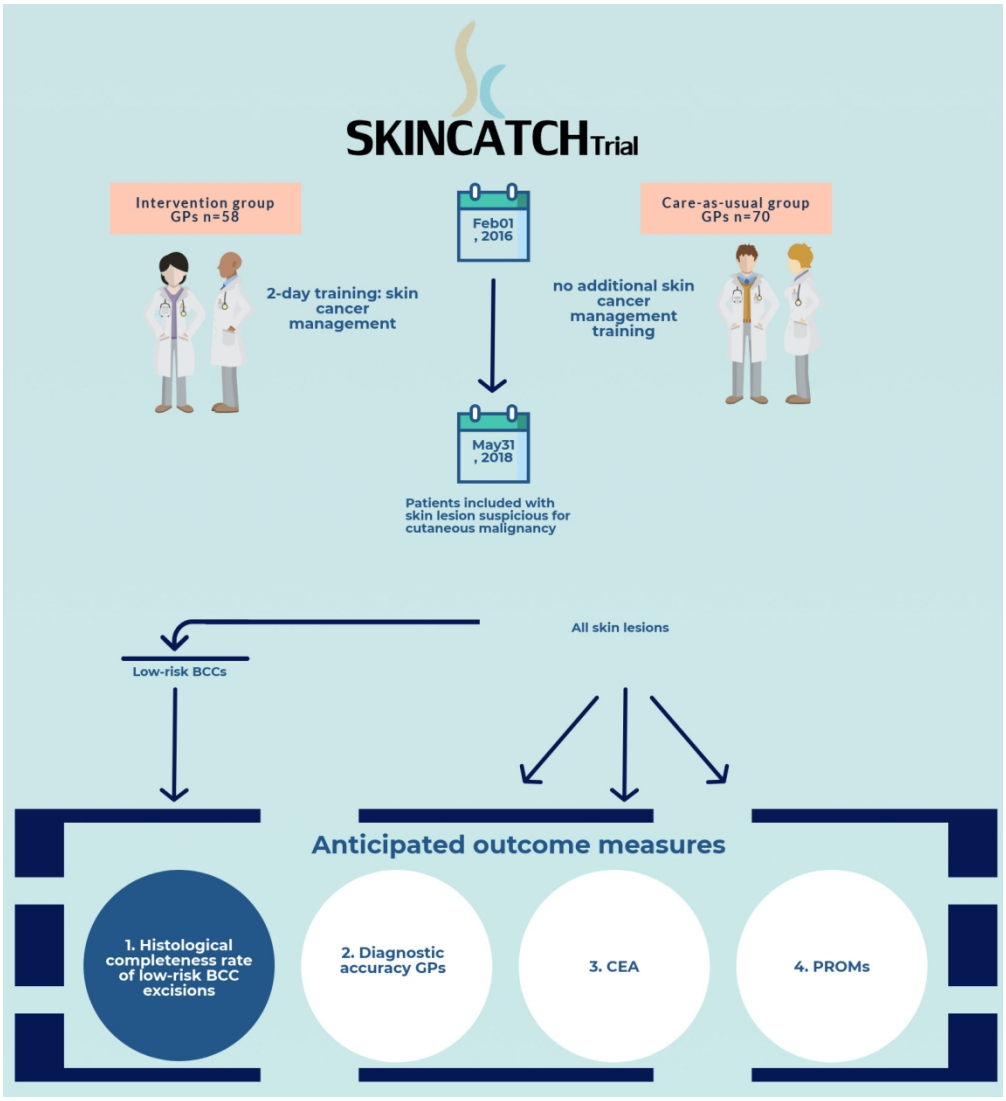


Design SKINCATCH Trial

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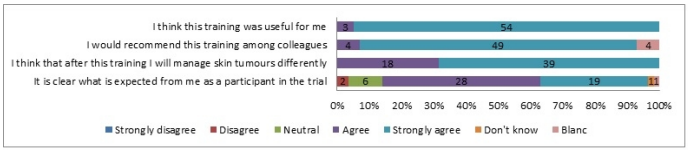


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# Supplementary material

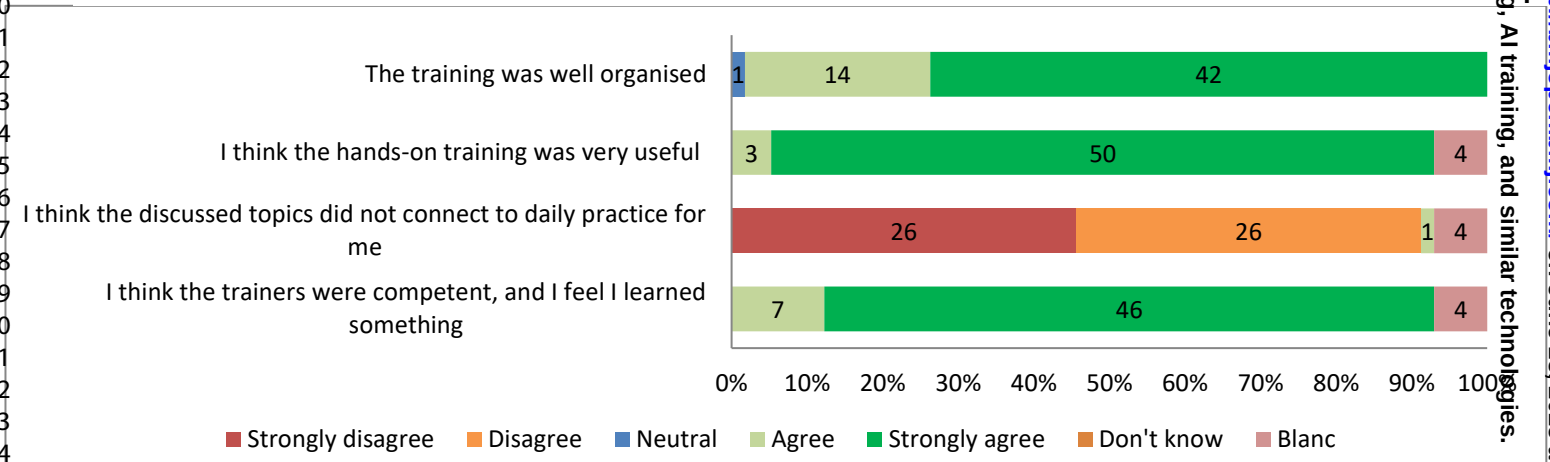
## Supplementary tables

**Table S1: Characteristics of GPs participating in the focus group meetings.**

| | Focus group 1 | Focus group 2 | Focus group 3 | Total |
|---|---|---|---|---|
| Total, n | 8 | 5 | 4 | 17 |
| | | | | |
| Intervention group, n(%) | 4 (50) | 2 (40) | 3 (75) | 9 (53) |
| Male, n(%) | 4 (50) | 2 (40) | 1 (25) | 7 (41) |
| Age, median (IQR) | 51 (43-57) | 49 (41-62) | 36 (35-52) | 49 (39-57) |
| Years of professional experience, median (IQR) | 17 (12-22) | 16 (7-30) | 8 (7-25) | 14 (8-25) |
| Professional environment, n(%) | | | | |
| Individual practice | 2 (25) | 1 (20) | 0 (0) | 3 (18) |
| Duo practice | 2 (25) | 3 (60) | 2 (50) | 7 (41) |
| Group practice or medical centre | 4 (50) | 1 (20) | 2 (50) | 7 (41) |
| | | | | |
| *Abbreviations: GP, general practitioner; IQR, interquartile range* | | | | |

## Supplementary figures

**Figure S1: Additional outcomes of the training evaluation survey.**

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# Appendices

## Appendix A

Training evaluation survey February 2016.

| Statement | Strongly disagree | Disagree | Neither agree or | Agree | Strongly agree | Don't know | No opinion | Not filled in |
|---|---|---|---|---|---|---|---|---|
| 1.I would recommend this training for my colleagues. | | | | | | | | |
| 2. The hands-on part using human specimen was useful. | | | | | | | | |
| 3. The subjects of the training did not reflect daily practice. | | | | | | | | |
| 4. The teachers were competent, I learned something today. | | | | | | | | |
| 5. The training was well organised. | | | | | | | | |
| 6. It was clear was it expected from me as a participant in the trial. | | | | | | | | |
| 7. After this training, I will manage patients with skin cancer differently. | | | | | | | | |
| 8. This training was useful for me. | | | | | | | | |

## Appendix B

Trial evaluation survey November 2016.

Q1: In which study group are you randomized?

a. Intervention group
b. Care as usual group

Q2: How many patients did you include in the trial? ….

Q3: Statement; I do see patients with cutaneous lesions suspicious for a malignancy. The reason I do not include them in the trial are…

a. Lack of time
b. I don't understand the study forms
c. The trial restricts me in skin cancer excisions
d. I am afraid to do skin surgery
e. The patients declined
f. Financial reasons
g. I realize I could have included patients afterwards
h. I don't want to include patient because then I have to treat them differently
i. Other: ….

Q4: Numbers show that GPs should see around 5 patient a year who meet the criteria for low-risk basal cell carcinomas (i.e., <1cm, non-aggressive subtype, primary tumour, low-risk locations).

a. I see less than 5 patients
b. I see 5 patients, but I don't include them



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c. I see more than 5, but I don't include them
d. Other: ….

Q5: Statement; it would be easier for me to only include patients with a skin lesion suspected for low-risk basal cell carcinoma, instead of patient with a skin lesion suspected for a malignancy in general.

a. Agree
b. Disagree
c. It does not matter

Q6: How often would you like to be reminded by us for including patients in the trial?

a. Weekly
b. 2-weekly
c. Monthly
d. Other: ….

Q7: Do you think it would be easier to include patients if these consultation were clustered?

a. Yes
b. No

Q8: Do you have any ideas how we can make it more easy for you? All ideas are welcome! …

Q9: Do you have any final remarks? …

## Appendix C

Medical record analysis.

| Selected ICPC codes | |
|---|---|
| S04 | Localised tumour skin/subcutis |
| S05 | Multiple tumours skin/subcutis |
| S06 | Localised redness/erythema of the skin |
| S21 | .01 Dry skin/ squamae<br>.02 Lichenification/induration |
| S26 | Fear for cancer of the skin/subcutis |
| S77 | .01 Basal cell carcinoma<br>.02 Squamous cell carcinoma<br>.03 Malignant melanoma<br>.04 Kaposi sarcoma |
| S79 | .01 Dermatofibroma |
| S80 | .01 Dysplastic naevus |
| S82 | Naevus/mole |
| S99 | .01 Granuloma pyogenicum<br>.02 Seborrheic keratosis<br>.03 Rosacea<br>.04 Vitiligo<br>.05 Discoid lupus erythematosus<br>.06 Lichen planus<br>.07 Striae |



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| | |
|---|---|
| | .08 Erythema nodosum<br>.09 Keloid<br>.10 Keratoacanthoma<br>.11 Actinic keratosis |

## Appendix D

**Introduction**

- Introduction
- Background and aim of study
- Aim and structure of interview
- Informed consent forms, permission audio-taping, demographic questionnaire to be filled in
-

**Part 1: Experiences with the SKINCATCH Trial**

- General experiences with the trial

**Part 2: Perceived barriers related to the low inclusion rate**

- Perceived barriers related to the low inclusion rate of low-risk BCCs in the trial

**Part 3: Perceived barriers related to the implementation of the trial (low excision rate)**

- Perceived barriers related to the low excision rate

**Part 4: Suggestions to facilitate implementation in the future**

- Practical solutions to facilitate implementation

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# Process evaluation of a multi-centre randomized clinical trial of substituting surgical excisions of low-risk basal cell carcinomas from secondary to primary care



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# Process evaluation of a multi-centre randomized clinical trial of substituting surgical excisions of low-risk basal cell carcinomas from secondary to primary care

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## Article Summary – Strengths and limitations of this study

- A strength is that this process evaluation uses complementary descriptive quantitative measures as well as qualitative measures at different time points during the course of the trial.
- It provides essential in-depth insight into general practitioners' exposure to the intervention, implementation of the intervention, and their experiences with the intervention and trial.
- A limitation of our study is the late conduction of a barrier analysis instead of addressing identified barriers prior to the onset of the trial.


## Abstract

**Objectives**

In 2016 the SKINCATCH Trial, a clustered multi-centre randomized trial, was initiated to assess whether low-risk basal cell carcinomas (BCCs) can be treated by general practitioners (GPs) without loss of quality of care. The trial intervention consisted of a tailored 2-day educational course on skin cancer management. The aim of this process evaluation was to investigate GPs' exposure to the intervention, implementation of the intervention, and experiences with the intervention and trial.

**Research design and methods**

Data on exposure to the intervention, implementation and experiences was obtained at several points during the trial. Complementary quantitative components (i.e. surveys, database analysis, medical record analysis) and qualitative components (i.e. interviews and focus groups) were used. Quantitative data were analysed using descriptive statistics; qualitative data were summarized (barrier interviews) or audio-recorded, transcribed verbatim and thematically analysed using Atlas.Ti (focus groups).




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**Results**

Following a 100% intervention *exposure*, results concerning the *implementation* of the trial showed that aside from the low inclusion rate of patients with low-risk BCCs (n=54), even less excisions of low-risk BCCs were performed (n=40). Although the intervention was *experienced* as highly positive, several barriers were mentioned regarding the trial including administrative challenges, lack of time and high workload of GPs, low volume of BCC patients and patients declining to participate or requesting a referral to a dermatologist.

**Conclusions**

Although GPs' participation in the highly valued training was optimal, several barriers may have contributed to the low inclusion and excision rate of low-risk BCCs. While some of the issues were trial-related, other barriers such as low patient-volume and patients requesting referrals are applicable outside the trial setting as well. This may question the feasibility of substitution of surgical excisions of low-risks BCCs from secondary to primary care in the current Dutch setting.

**Trial registration number**: Trial NL5631 (NTR5746)

## Key words (3-10)

Skin cancer, basal cell carcinoma, dermatology, primary care, general practitioner, substitution of care

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## Background

Health care is becoming increasingly expensive with rising percentages of the gross domestic product spent on health care.[1-3] Since research has shown health systems with stronger primary care tend to have lower health care costs, initiatives such as substitution of hospital care towards primary care are increasingly developed and experimented with worldwide.[4-13] The main goal of these initiatives is to maintain the affordability, and thus sustainability, of healthcare. Furthermore, it is a means to provide more easily accessible care closer to the patients' home. However, not every type of care may be suitable for substitution towards primary care. Whether a particular type of care is deemed appropriate for substitution depends on various disease and care specific factors, such as high-volume and being low-complex care, and the support of different stakeholders including general practitioners (GPs), medical specialists, and patients.[5]

One type of care that has been conceived as a potential candidate for substitution of hospital care towards primary care is low-risk skin cancer care.[5 14] In the Netherlands, as in several other countries such as the UK and Australia, GPs have a gatekeeper function.[5 15 16] Consultations are mainly patient driven, and GPs, who until recently did not have a related primary care guideline, determine whether patients need access to secondary and tertiary healthcare.[17] A substantial proportion of patients with a BCC (60% in a comprehensive Dutch primary care database analysis) are referred to the dermatologist.[18-21] The idea of substituting low-risk skin cancer care to GPs is reflected in the recently published guideline 'suspicious cutaneous lesions' of the Dutch College of General Practitioners, which includes recommendations for GPs on the diagnosis and treatment of low-risk BCCs.[17] Particularly, low-risk basal cell carcinomas (BCCs) (i.e., non-aggressive histological subtypes, low-risk locations and size <2 cm) are relatively easy to diagnose and treat. Minor surgery can be performed in primary care offices, and innovations such as teledermatology can support GPs.[22 23]

In 2016 the SKINCATCH Trial (SKIN Cancer And Tumour Health Care) was initiated to assess whether low-risk BCCs can be treated by GPs without loss of quality of care. The study design was a multi-



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centre cluster randomized non-inferiority trial, in which the intervention included a tailored 2-day educational course on skin cancer management. Participating GPs showed great enthusiasm and interest at the start of the trial [14], and although the patient inclusion rate of all skin tumours suspicious for skin cancer was consistent with the researchers' expectations, the inclusion rate of low-risk BCCs (primary outcome) lagged far behind.

Therefore, a process evaluation was conducted alongside the trial. A process evaluation is crucial for providing insight in to what extent the trial intervention was actually implemented, how it was experienced by study participants and whether the intervention is feasible in daily practice.[24 25] The results can be used to guide the implementation of similar care substitution initiatives.[24] The aim of our process evaluation was, therefore, to assess GPs' exposure to the intervention, implementation of the intervention, and experiences with the intervention and trial.

## Methods

### *Description of SKINCATCH Trial*

The SKINCATCH Trial (see Figure 1) was initiated based on the hypothesis that conventional excision of low-risk BCC could be performed by GPs in a primary care setting while maintaining the same quality of care. The study design was a multi-centre cluster randomized non-inferiority trial, with GP practices (including group practices) being included as clusters. These clusters were randomized into two parallel arms: the intervention group, which was trained before starting the trial, and the care-as-usual group. Main outcomes included the histological completeness rate of low-risk BCC excisions by GPs in the intervention group compared to dermatologist (primary outcome), diagnostic accuracy of GPs regarding skin tumours, cost-effectiveness of the intervention and treatment and patient reported outcomes regarding preferences and cosmetics (secondary outcomes) (see Table 1).

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The GPs in the intervention group were offered an extensive training in BCC (and skin tumour) management consisting of a tailored 2-day educational course including hands-on surgical training in cadaveric workshops. The GPs in the care-as-usual group did not receive the 2-day educational intervention and were asked to provide skin cancer care the way they were used to. As compensation, they were offered the same BCC management training after completion of the trial. Eligible patients (i.e., all patients with a skin tumour suspicious for malignancy) were to be included in the trial during the period February 2016 to May 2018. The first patient was enrolled on Feb 23 2016. Included patients were asked to complete questionnaires at start of their treatment, and 3 and 6 months post-treatment.

**Figure 1: Overview of SKINCATCH Trial design.**

*Abbreviations: BCC, basal cell carcinoma; CEA, cost-effectiveness analysis; GP, general practitioner; PROMs, patient reported outcome measures.*

The power analysis for the primary outcome was based on a t-test of the proportion of histological completeness of the physicians (GPs and dermatologists), where the physician is the unit of analysis. We expected 5 eligible patients in the non-inferiority part of the trial per GP per year, which was based on national incidence rates and a prior GP survey.[26 27] Using a non-inferiority margin of 5% (based on a clinically accepted margin) and a one-sided significance level of 2.5%[28], a sample size of 45 GPs per group (90 GPs total) was required to obtain a power of 80%. This sample size was increased to 129 GPs to account for (1) the possibility of drop-outs of GPs, and (2) the effect of within-practice correlations of the GPs.

**Table 1: Interventions, recommendations and outcome measures of the SKINCATCH Trial.**

| | |
|---|---|
| Main components of interventions for intervention group | A tailored 2-day educational course regarding the diagnosis and management of skin cancer with a focus on BCCs including hands-on surgical training (cadaveric workshops) |
| | An interactive 20 minute e-learning for GPs, which was available at all times during the trial |
| Main recommendations for low-risk BCC care to be | When a skin tumour is suspicious for a malignancy, a biopsy should be performed |



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| performed by GPs in intervention group | If the histopathological examination confirms a low-risk BCC, the GP should perform the excision with adequate margins |
| | If the histopathological examination shows a high-risk BCC or other type of skin cancer, the GP should refer the patient to the dermatologist |
| Main outcome measures | Histopathological completeness rate of low-risk BCC excisions by GPs in the intervention group compared to dermatologists |
| | Diagnostic accuracy of skin tumours |
| | Patient reported outcome measures concerning preferences on treating physician and cosmetic results of the received treatment |
| | Cost-Effectiveness Analysis |

*Abbreviations: BCC, basal cell carcinoma; GP, general practitioner.*

A total of 600 patients with a suspicious skin tumour were included in the trial; 316 patients were included by the GPs in the intervention group and contained 54 patients with a low-risk BCC (9% of the needed sample size for sufficient statistical power [n=600]). As recruitment of removed BCCs was so low, we are unable to report on the primary outcome of the trial (histological completeness rate of low-risk BCC excisions by GPs in the intervention group compared to dermatologists). The process evaluation presented in this paper was based on this low inclusion rate of low-risk BCCs.

**Ethics, consent and permissions**

Ethical approval for the SKINCATCH trial study was granted by the medical ethics committee of the Erasmus University Medical Centre in Rotterdam (MEC-2015-492). All participants have provided written informed consent. As this process evaluation is an evaluation among trial participants, conducted as integral part of the trial, we did not obtain separate ethical approval, except for the focus groups. The SRQR guidelines were applied, as far as applicable. These guidelines provide a tool for the transparent reporting of qualitative studies.[29]

### *Design process evaluation*

In designing this process evaluation we used the framework of Hulscher et al.[24] to gain insight into the processes responsible for the (variation in) results in the target group. Data on exposure to the intervention, implementation of the intervention, and experiences with the intervention and trial



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were obtained. We used both quantitative and qualitative components, which are described in detail below.

## *Data collection, outcome measures and analyses*

### Surveys

Two types of surveys were conducted among participating GPs during the course of the trial to assess their *exposure* to the intervention and their *experiences with the intervention and trial*: a training evaluation survey and an online trial evaluation survey. Participation in each of the surveys was voluntary.

Training evaluation survey – After completing the pre-study training all GPs were asked to complete a survey to evaluate the training. With this survey, both their *exposure to and experiences with the training* were assessed. The survey consisted of 8 statements (7 statements on the content of the training, and 1 statement on the organisation of the training) using a five-point Likert-scale ranging from *strongly disagree* to *strongly agree* (Appendix A).

Trial evaluation survey – Ten months after the start of the trial, an online survey was sent to all participating GPs to further explore their *experiences with the trial*. The survey consisted of 4 multiple-choice questions, focussing on experiences with the trial and assessing the perceived barriers (Appendix B).

Training and trial evaluation surveys were analysed separately using SPSS 24.0 statistical software.

### Database analysis

To gain insight into *the implementation of the intervention* and more specifically the low inclusion rate of BCC patients, a database analysis at the end of the inclusion period was performed investigating the number of inclusions for the primary outcome measure of the trial (i.e. histological completeness of low-risk BCC excisions) based on the paper or digital case report forms (CRF)(i.e.,



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OpenClinica).[30] The CRF included (among others) information on tumour characteristics (e.g., size and location), the histopathological diagnosis of the skin tumour and whether or not the GP performed a surgical excision. The CRFs in OpenClinica were exported to and analysed with SPSS 24.0 statistical software. Descriptive statistics were used to assess the number of performed low-risk BCC surgical excisions as compared to the number of included low-risk BCCs.

**Medical record analysis**

A medical record analysis was performed to further explore the *implementation of the intervention* by obtaining quantitative information regarding the number of potential eligible patients and potential eligible excisions. This analysis was performed among 7 randomly selected GPs in two primary care practices, participating in the intervention group of the trial. All GP records from February 2016 to February 2017 were screened for eligible patients by a GP practice healthcare assistant using International Classification of Primary Care (ICPC) codes for skin tumours (Appendix C). Information was obtained on number of patients, clinical diagnosis of the GP, size of the tumour, localisation of the tumour, and choice of treatment. In case of histopathological examination additional information was obtained on histopathological diagnosis from the biopsy and/or excision, and histological completeness in case of surgical excision. If the patient was referred to secondary care information was obtained on clinical or histopathological diagnosis. Descriptive statistics were used to assess the GPs' management of eligible patients.

**Telephonic 'barrier' interview**

Six months after the initiation of the trial, telephonic interviews were conducted by one of the researchers (EN) to identify GPs' *experiences with the trial* in terms of perceived barriers regarding the inclusion of patients. We invited GPs from both arms either with no inclusions or one or more inclusions to participate. After 12 interviews with GPs in the intervention group and 10 GPs in the care-as-usual group no new barriers emerged. The semi-structured interviews were conducted between August and November 2016. The data was analysed by the researcher conducting the



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telephonic interview (EN), noting reported elements during the interview and descriptively summarizing the main barriers afterwards.

**Focus groups**

Three focus groups were conducted between December 2017 and March 2018 to gain an in-depth understanding of GPs' *experiences with the intervention and the trial*. Focus groups were chosen as these facilitate interaction between participants, enabling us to identify the GPs' views on substitution of care, and their experiences with the trial.[31-33] All GPs participating in the trial were invited by email, containing an information leaflet about the qualitative evaluation study. GPs could register for one of the three organized focus groups by contacting one of the researchers.

The sessions were moderated by an experienced independent qualitative researcher (ML) and an assistant, both not being involved in the trial. One of the SKINCATCH Trial researchers (EN) was present during the focus groups, but only to answer substantive questions regarding the trial.

In each focus group, the discussion was semi-structured using a predefined topic list consisting of two separate parts: general views on substitution of care (part 1) and GPs' experiences with the trial (part 2). The current study focusses on the latter part (Appendix D). Results on their general views on substitution of care have been described elsewhere.[14]

All focus groups were audio-recorded with consent of participants. Subsequently, the audio tapes were transcribed verbatim and imported to Atlas.ti (version 8 for Windows) for analysis.

Two researchers (EN, ML) independently openly-coded the first transcript after which the obtained codes were discussed and a preliminary coding scheme was developed. Next, all transcripts were coded by one researcher (EN or ML) and subsequently checked by a second researcher (EN or ML). Differences were discussed and refined until agreement was reached, and new codes were added when needed. The initial coding phase was followed by the phase of constant comparison.[31] Different



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codes were compared and the relationship between codes were explored to detect emerging themes.

## Results

### *Participants*

A total of 128 GPs from 90 different primary care practices were included for randomisation (Table 2). One GP in the intervention group, and 22 GPs in the care-as-usual group dropped out. Most drop outs occurred within 3 months after the start of the trial. Reported reasons mostly concerned lack of time and personal illness. All 128 GPs were included for the database analysis, and a subgroup of 7 GPs (12%) of the intervention group were included for the medical record analysis. See Table 2 for more information on the participants of the different quantitative and qualitative components. For further details regarding the focus groups see Supplementary table S1.

**Table 2: Participants (GPs) of the SKINCATCH Trial and each of the components of the process evaluation**

| *SKINCATCH Trial* | Intervention group (n=58) | Care as usual group (n=70 |
|---|---|---|
| Male, n(%) | 32 (54) | 33 (47) |
| Drop outs, n(%) | 1 (2) | 22 (31) |
| | | |
| *Quantitative components*, n(%) | | |
| Database analysis | 58 (100) | 70 (100) |
| Medical record analysis | 7 (12) | N/A |
| Training evaluation survey | 57 (98) | N/A |
| Trial evaluation survey | 24 (41) | 36 (51) |
| | | |
| *Qualitative components*, n(%) | | |
| Telephonic 'barrier' interview | 12 (21) | 10 (14) |
| Focus groups | 9 (16) | 8 (11) |
| Focus group 1 (n=8) | 4 (50) | 4 (50) |
| Focus group 2 (n=5) | 2 (40) | 3 (60) |
| Focus group 3 (n=4) | 3 (75) | 1 (25) |

*Abbreviations: GP, general practitioner*

### *Exposure to the intervention*

All GPs in the intervention group (n=58) completed the extensive 2-day training program. Regarding the e-learning, it was not possible to measure the exposure quantitatively; it could be openly



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accessed by GPs at all times. The focus groups suggested that a wide variation existed regarding the exposure to the e-learning. Whereas some GPs stated to have gone through the files, others reported not remembering it have been offered or not to have opened it due to time restrictions.

### *Implementation of the intervention*

Only 54 patients with low-risk BCC (9% of needed sample size) of the total of 600 patients with suspicious skin tumours were included in the trial. Furthermore, the GPs in the intervention group performed 95 surgical excisions of skin tumours in total, of which 40 concerned a low-risk BCC. In the care as usual group 29 of the 284 included patients concerned patients with histopathological confirmed low-risk BCCs.

The medical record analysis of potentially eligible BCCs patients in one year among 7 GPs resulted in 448 potential patients. After manual extraction by two of the authors (EN, KR), 35 confirmed BCC patients remained of which 16 were low-risk BCC. Three BCCs (19%) were excised by two of the seven GPs; the remaining 13 tumours were not excised by the GP. Reported reasons in the medical records were: preference for topical treatment (n=2), patient preference for dermatologist (n=1), referral due to melanoma in differential diagnosis (n=1), coinciding melanoma (n=1), not reported in medical record (n=8).

### *Experiences with the intervention and trial*

#### ***Experiences with the intervention***

*Training evaluation survey* - The training was generally evaluated positively by the GPs (Figure 2); almost all (n=54) indicated to have found the training useful and almost all (n=53) indicated they would recommend the training among colleagues. All GPs (strongly) agreed with the statement the training would change the way they manage skin cancer, and the vast majority (n=47) confirmed that



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it was clear to them what was expected regarding their participation in the trial. For further details on the training evaluation survey see Supplementary figure S1.

**Figure 2: Results from the training evaluation survey.**

*Focus groups* – The focus groups confirmed that the GPs were highly positive about the training. Some reported it to be the best training they have ever had. According to the GPs it offered them guidance in managing skin tumours in general, and it was particularly useful to learn techniques for minor surgery hands-on. GPs indicated to feel more empowered to extend their services regarding skin tumour management in daily practice. However, some GPs did mention that with time passing they returned to old patterns. According to the GPs, the training may not have been enough for all GPs to change their role in the management of skin tumours. Furthermore, according to some GPs the participation in the trial caused them to diminish their role in skin cancer management as they were used to performing minor surgery on high(-er) risk skin cancers (e.g., BCCs located in the face), which was restricted by the study protocol. Regarding the e-learning, the few GPs who used the e-learning were generally positive and reported it was fun to do.

***Experiences with the trial***

*Trial evaluation survey* – Reported reasons for the low number of included (BCC) patients in the trial concerned lack of time (n=34) and realizing the patients' eligibility afterwards (n=27), patients rejected participation (n=11), not understanding the different study forms (n=5), the trial restricts me on performing excisions due to trial recommendations (n=3), the GP being afraid to perform minor surgery (n=1) and having to treat the patient different from what they were used to (n=1). A smaller group of GPs (n=13) agreed with the statement that it would make it easier for them to only include patients with a low-risk BCC rather than all skin cancers, and the largest part (n=44) disagreed with



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the option of clustering consultation hours for skin cancer patients for GPs individually to make patient recruitment more easy.

*Telephonic 'barrier' interview* – During the telephonic interview six barriers were identified. Main perceived barriers reported by the GPs concerned ambiguity regarding eligibility criteria of patients, and lack of clarity regarding the trials' CRFs. GPs indicated that they expected one of the researchers to visit their practices for one-on-one explanation on the forms. Further perceived barriers included the trial not being a priority, the inclusion process being too time-consuming, difficulty retaining information over time, and discouragement due to refusal of patients or skin tumours appearing high risk.

*Focus groups* –GPs' experiences regarding the trial varied. Whereas some GPs were positive about the trial and managed to include patients (up to 53), others reported rather negative experiences. Several barriers were identified which may have contributed to the relatively low inclusion rate (both in general as well as concerning low-risk BCCs). First, *administrative challenges* related to the inclusion of patients to the trial were reported as a barrier. According to the GPs, the inclusion procedure (informed consent procedure and CRF) was difficult to integrate in daily practice with several study forms needed to be completed at different times during the treatment course of the patient. GPs reported this to be difficult and too time-consuming. However, GPs lacked suggestions on how to improve these administrative challenges as they know it is crucial for data collection. Some GPs reported to have experienced the start of the trial as rather confusing; they stated study forms were not immediately present, and that both the start-date for inclusion as well as the eligibility criteria were not clear. Others were more positive and reported to have found a way of structuring it for themselves, and commented that inaccuracies were picked up well by the researchers. The online CRF application (i.e., OpenClinica) was variably received by the GPs, though it was specifically designed for the trial in an attempt to facilitate the GPs in data registration. Some GPs reported it to be not user-friendly and continued using the paper forms, while others stated it to



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be of great help. Suggestions on reducing the administrative challenges included having researchers collect the data themselves by visiting the GPs' practices and using an automated digital data collection programme.

Another reported barrier related to the administrative barrier, was a perceived *lack of time and high workload* to include patients. According to the GPs, this was related to cramped consultation hours, being behind schedule, and patients presenting multiple problems during consultation with their GP in which the skin tumour was not perceived as the main issue. As a result of the lack of time and high workload, GPs were more hesitant to recruit patients as this would consume additional time.

A third barrier as reported by the GPs was the *low volume of eligible patients* seen in practice. GPs reported to only see a small number of low-risk BCC annually. Some also stated to have seen less BCC patients during the course of the trial than anticipated, for reasons not clear.

A fourth barrier reported were *patients declining or refusing to participate* in the trial. According to the GPs, some patients did not want to participate due to the difficulty and large amount of information they had to read upon participation request, and things needed from them after inclusion (i.e., questionnaires). The GPs further mentioned that especially older patients and patients less intelligent often declined to participate.

In addition to the low inclusion rate, the GPs were also asked for possible explanations for the low rate of excisions performed by GPs during the trial. Whereas some GPs indeed reported to have only performed few excisions, others were rather surprised hearing this as it did not align with their own experiences. Reported reasons for the low number of excisions were the low number of BCC patients seen in daily practice, patients requesting a referral to the dermatologist, a lack of time and high workload, having a colleague who performs all the excisions, and the training course not being sufficient to change GPs' behaviour, particularly considering the reported already high workload.

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## Discussion

This evaluation study showed that, although GPs initially showed great enthusiasm towards the concept of substitution[14], and all GPs participated in the highly valued training, several barriers may have contributed to the low inclusion and excision rate of low-risk BCC patients. Some of these barriers seem to be attributable to the trial setting (e.g., administrative challenges, patient recruitment issues), complicating its implementation in daily practice. However, other reported barriers such as high workload, low volume of low-risk BCC patients and patients requesting a referral, apply outside the trial setting as well.

Although several trial-related barriers, such as clear study forms and inclusion criteria, should have been adequately addressed in the current trial, other practical issues such as patient recruitment challenges are commonly reported problems within (multicentre) randomised controlled trials (RCTs) and are difficult to prevent completely.[34-38] Similarly, the reported barrier of lack of time/high workload of GPs seems to be inherently related to GP practices[38-40], and may have further impeded study implementation. To tackle these barriers, targeted interventions to enhance recruitments skills of GPs may be valuable to optimize the feasibility of trial interventions in clinical medical care.[38]

In addition to the trial-related barriers, other reported barriers also apply outside the trial setting and concern the topic of substituting low-risk BCC care towards primary care. Despite high and rising incidence rates of BCCs reported in the literature[27 41], we found that only a small proportion of BCCs can be considered 'low-risk' when taking into account body site, diameter and histological subtype[41-43], which was recently confirmed by Fremlin et al.[42] Aside from the low volume, the number of excisions performed by GPs in the intervention group was even lower. According to the GPs this may have been partly related to the training being insufficient to change GPs' practices. Also, GPs were less inclined to perform a surgical excision when patients requested a referral to a dermatologist, which has been found in previous studies as well.[14 15 44-48] These barriers, related to feasibility, need



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to be addressed, where possible, before assessing whether low-risk BCCs can be treated by GPs without a loss of quality of care.

Indeed, with the patient volume being this low (based on the medical record analysis approximately 2 patients with low-risk BCC per GP per year), it will be challenging, if not impossible, for GPs to obtain and maintain their competencies in low-risk BCC management.[14 42] Particularly in the context of this low patient volume, a one-day training may not be sufficient to acquire the relevant competencies. Offering adequate training in a repetitive setting tailored to the specific needs of each GP may therefore contribute to a better integration of what is learned into daily practice.[49 50] Although this was attempted by offering an e-learning module, the uptake (although variable) seemed to be only minimal. Furthermore, the cost-effectiveness of such interventions may be questioned. Other solutions may focus on organizational changes in primary care such as concentrated substitution.[14] Within this concept GPs refer patients to a colleague GP with noted interest, experience and competence in skin cancer care, thereby clustering these patients within or between practices.[14]

A limitation of our study includes the late conduction of a barrier analysis. Implementation of change is a complex process, and a preceding barrier analysis among all involved stakeholder groups is advocated to increase the success of interventions.[51] By addressing identified barriers prior to the onset of this trial, failure may have been prevented. In addition, such input can serve to promote awareness and stimulate involvement among the target groups, incentivizing more successful adoption at a later stage.[52] However, it is also important to elicit views of stakeholders who already have some experience with the intervention at hand, as this often elicits different types of barriers.[14] Performing a barrier analysis both before the onset of the trial as well as during the trial as part of a process evaluation is therefore advised.

A strength of this study is that we used several complementary evaluation methods, combining both quantitative and qualitative data at different time points during the course of the trial, focusing on



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both the intervention and care-as-usual group. Although only a low number of GPs was included in the medical record analysis and data on the use of the e-learning module was lacking, by using triangulation of data we were able to capture different dimensions of the observed phenomena. As such, our process evaluation provides essential in-depth insight into the trial and the observed outcomes.

## Conclusions

This process evaluation has identified some trial-related as well as more general topic-related barriers that may be responsible for the low inclusion and excision rate of low-risk BCC patients by GPs within the trial. Based on the results of this study, without being able to measure the surgical effectiveness of GPs, the feasibility of substituting low-risk BCC care from secondary to primary care in the current setting should be questioned. Future trials on care substitution may benefit from thorough qualitative barrier analyses among all involved stakeholders, before onset as well as during the course of the trial, to increase the likelihood of successful implementation.

**List of abbreviations**

BCC, basal cell carcinoma; CRF, case report form; GP, general practitioner; ICPC, International Classification of Primary Care.

## Declarations

### *Ethics approval and consent to participate*

Ethical approval for the SKINCATCH Trial was granted by the medical ethics committee of the Erasmus University Medical Center in Rotterdam (MEC-2015-492). All participants have provided written informed consent. As this process evaluation is an evaluation among trial participants, conducted as integral part of the trial, we did not obtain separate ethical approval except for the focus groups.



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## *Consent for publication*

Not applicable.

## *Availability of data and material*

The data that supports the findings of this study are available from the medical ethics committee of the Erasmus University Medical Center in Rotterdam (Contact: Interview study reference number MEC-2016-204 and Focus group study reference number MEC-2015-492), but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of the medical ethics committee of the Erasmus University Medical Center in Rotterdam.

## *Patient and public involvement*

This research was done without patient involvement. Patients were not invited to comment on the study design and were not consulted to develop patient relevant outcomes or interpret the results. Patients were not invited to contribute to the writing or editing of this document for readability or accuracy.

## *Competing interest*

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: the principal investigator received an institutional grant as financial support from Foundation Achmea Healthcare for the submitted work; no other relationships or activities that could appear to have influenced the submitted work.

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## Author contributions

EN, ML, MW, KR, RB, PB, TN involved in the concept and design of the quantitative and qualitative study. EN, ML performed the focus groups. EN, ML, KR involved in quantitative and qualitative data acquisition. EN, ML, MW, RB, PB, TN involved in data analysis and interpretation. The paper was written by EN and ML, and was critically revised by all authors. All authors read and approved the final manuscript.

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## References

1. Alberto M, David M, Luca L, et al. Future trends in health care expenditure. 2017 doi: doi:https://doi.org/10.1787/247995bb-en
2. OECD. Better Ways to Pay for Health Care2016.
3. Mackenbach JP. [What are the health benefits of the most expensive healthcare system in Europe?]

Wat levert de duurste gezondheidszorg van Europa ons op? *Ned Tijdschr Geneeskd* 2015;159:A9433. [published Online First: 2015/08/27]
4. de Jong J, Korevaar J, M. K, et al. Substitution potential between primary and secondary health care. www.nivel.nl: NIVEL, 2016:50.
5. Van Dijk C, Korevaar J, De Jong J, et al. Room for substitution? Shift from secondary to primary care. . NIVEL: NIVEL, 2013:109.
6. van Hoof SJ, Kroese ME, Spreeuwenberg MD, et al. Substitution of Hospital Care with Primary Care: Defining the Conditions of Primary Care Plus. *Int J Integr Care* 2016;16(1):12. doi: 10.5334/ijic.2446 [published Online First: 2016/09/13]
7. van Hoof SJ, Spreeuwenberg MD, Kroese ME, et al. Substitution of outpatient care with primary care: a feasibility study on the experiences among general practitioners, medical specialists and patients. *BMC Fam Pract* 2016;17:108. doi: 10.1186/s12875-016-0498-8

10.1186/s12875-016-0498-8 [pii] [published Online First: 2016/08/11]
8. Fortney JC, Steffick DE, Burgess JF, et al. Are Primary Care Services a Substitute or Complement for Specialty and Inpatient Services? *Health Services Research* 2005;40(5p1):1422-42. doi: doi:10.1111/j.1475-6773.2005.00424.x
9. Laurant M, Reeves D, Hermens R, et al. Substitution of doctors by nurses in primary care. *Cochrane database Syst rev* 2005;2(2):CD001271.



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10. Martínez-González NA, Djalali S, Tandjung R, et al. Substitution of physicians by nurses in primary care: a systematic review and meta-analysis. *BMC Health Services Research* 2014;14(1):214. doi: 10.1186/1472-6963-14-214
11. Weller DP. Workforce substitution and primary care. *Med J Aust* 2006;185(1):8-9. doi: wel10579_fm [pii] [published Online First: 2006/07/04]
12. Yong CS. Task substitution: the view of the Australian Medical Association. *Med J Aust* 2006;185(1):27-8. doi: yon10552_fm [pii] [published Online First: 2006/07/04]
13. Starfield B, Shi L. Policy relevant determinants of health: an international perspective. *Health Policy* 2002;60(3):201-18. doi: S0168851001002081 [pii] [published Online First: 2002/04/20]
14. Noels EC, Wakkee M, Van den Bos R, et al. Substitution of low risk skin cancer hospital care towards primary care: a qualitative study on views of general practitioners and dermatologists. 2019
15. Greenfield G, Foley K, Majeed A. Rethinking primary care's gatekeeper role. *BMJ* 2016;354:i4803. [published Online First: 2016/09/25]
16. Moreno G, Tran H, Chia ALK, et al. Prospective study to assess general practitioners' dermatological diagnostic skills in a referral setting. *Australasian Journal of Dermatology* 2007;48(2):77-82. doi: doi:10.1111/j.1440-0960.2007.00340.x
17. Baaten GGG, Buis PAJ, Damen Z, et al. NHG-Standaard Verdachte Huidafwijkingen 2017 [Available from: https://www.nhg.org/standaarden/volledig/nhg-standaard-verdachte-huidafwijkingen.
18. van Dijk CE, Verheij RA, Spreeuwenberg P, et al. Minor surgery in general practice and effects on referrals to hospital care: Observational study. *BMC Health Services Research* 2011;11(1):2. doi: 10.1186/1472-6963-11-2
19. Lowell BA, Froelich CW, Federman DG, et al. Dermatology in primary care: Prevalence and patient disposition. *J Am Acad Dermatol* 2001;45(2):250-5. doi: S0190-9622(01)84392-9 [pii]

10.1067/mjd.2001.114598 [published Online First: 2001/07/21]
20. M.E. B-vD, Y.M. W, K. H, et al. Zorg door de huisarts. . *Jaarcijfers 2017 en trendcijfers 2011-2017* 2018 18-07-2018. (accessed 07-11-2018).
21. Wakkee M, Van Egmond S, Louwman M, et al. Opportunities for improving keratinocyte cancer care in primary and specialist care: a Dutch cohort study.
22. Eminovic N, Dijkgraaf MG, Berghout RM, et al. A cost minimisation analysis in teledermatology: model-based approach. *BMC Health Serv Res* 2010;10:251. doi: 1472-6963-10-251 [pii]

10.1186/1472-6963-10-251 [published Online First: 2010/08/27]
23. van der Heijden JP, de Keizer NF, Bos JD, et al. Teledermatology applied following patient selection by general practitioners in daily practice improves efficiency and quality of care at lower cost. *Br J Dermatol* 2011;165(5):1058-65. doi: 10.1111/j.1365-2133.2011.10509.x [published Online First: 2011/07/07]
24. Hulscher ME, Laurant MG, Grol RP. Process evaluation on quality improvement interventions. *Qual Saf Health Care* 2003;12(1):40-6. [published Online First: 2003/02/07]
25. Moore GF, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ : British Medical Journal* 2015;350 doi: 10.1136/bmj.h1258
26. de Vries E, Nijsten T, Louwman MW, et al. [Skin cancer epidemic in the Netherlands]

Huidkankerepidemie in Nederland. *Ned Tijdschr Geneeskd* 2009;153:A768. [published Online First: 2009/12/23]
27. Flohil SC, de Vries E, Neumann HA, et al. Incidence, prevalence and future trends of primary basal cell carcinoma in the Netherlands. *Acta Derm Venereol* 2011;91(1):24-30. doi: 10.2340/00015555-1009 [published Online First: 2011/01/26]
28. Head SJ, Kaul S, Bogers AJ, et al. Non-inferiority study design: lessons to be learned from cardiovascular trials. *Eur Heart J* 2012;33(11):1318-24. doi: ehs099 [pii]

10.1093/eurheartj/ehs099 [published Online First: 2012/05/09]



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29. O'Brien BC, Harris IB, Beckman TJ, et al. Standards for reporting qualitative research: a synthesis of recommendations. *Acad Med* 2014;89(9):1245-51. doi: 10.1097/ACM.0000000000000388 [published Online First: 2014/07/01]
30. Cavelaars M, Rousseau J, Parlayan C, et al. OpenClinica. *Journal of Clinical Bioinformatics* 2015;5(1):S2. doi: 10.1186/2043-9113-5-s1-s2
31. Green J, Thorogood N. Qualitative methods for health research. 3rd revised edition ed: Sage Publications Ltd 2014:233-254.
32. Krueger RA, Casey MA. Focus groups: a practical guide for applied research.: SAGE 2000.
33. Willis K, Green J, Daly J, et al. Perils and possibilities: achieving best evidence from focus groups in public health research. *Australian and New Zealand Journal of Public Health* 2009;33(2):131-36. doi: doi:10.1111/j.1753-6405.2009.00358.x
34. McDonald AM, Knight RC, Campbell MK, et al. What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies. *Trials* 2006;7:9. doi: 1745-6215-7-9 [pii]

10.1186/1745-6215-7-9 [published Online First: 2006/04/11]
35. de Wit NJ, Quartero AO, Zuithoff AP, et al. Participation and successful patient recruitment in primary care. *J Fam Pract* 2001;50(11):976. doi: jfp_1101_09760 [pii] [published Online First: 2001/11/17]
36. van der Gaag WH, van den Berg R, Koes BW, et al. Discontinuation of a randomised controlled trial in general practice due to unsuccessful patient recruitment. *BJGP Open* 2017;1(3):bjgpopen17X101085. doi: 10.3399/bjgpopen17X101085

bjgpopen17X101085 [pii] [published Online First: 2017/10/04]
37. Bower P, Wilson S, Mathers N. Short report: how often do UK primary care trials face recruitment delays? *Fam Pract* 2007;24(6):601-3. doi: cmm051 [pii]

10.1093/fampra/cmm051 [published Online First: 2007/09/18]
38. Foster JM, Sawyer SM, Smith L, et al. Barriers and facilitators to patient recruitment to a cluster randomized controlled trial in primary care: lessons for future trials. *BMC Med Res Methodol* 2015;15:18. doi: 10.1186/s12874-015-0012-3

10.1186/s12874-015-0012-3 [pii] [published Online First: 2015/04/19]
39. Croxson CH, Ashdown HF, Hobbs FR. GPs' perceptions of workload in England: a qualitative interview study. *Br J Gen Pract* 2017;67(655):e138-e47. doi: bjgp17X688849 [pii]

10.3399/bjgp17X688849 [published Online First: 2017/01/18]
40. van den Hombergh P, Kunzi B, Elwyn G, et al. High workload and job stress are associated with lower practice performance in general practice: an observational study in 239 general practices in the Netherlands. *BMC Health Serv Res* 2009;9:118. doi: 1472-6963-9-118 [pii]

10.1186/1472-6963-9-118 [published Online First: 2009/07/17]
41. Verkouteren JAC, Ramdas KHR, Wakkee M, et al. Epidemiology of basal cell carcinoma: scholarly review. *Br J Dermatol* 2017;177(2):359-72. doi: 10.1111/bjd.15321 [published Online First: 2017/02/22]
42. Fremlin GA, Gomez P, Halpern J. Are there sufficient numbers of low-risk basal cell carcinomas to justify general practitioners (family physicians) carrying out basal cell carcinoma surgery? *Clin Exp Dermatol* 2016;41(2):138-41. doi: 10.1111/ced.12718 [published Online First: 2015/07/21]
43. Lomas A, Leonardi-Bee J, Bath-Hextall F. A systematic review of worldwide incidence of nonmelanoma skin cancer. *Br J Dermatol* 2012;166(5):1069-80. doi: 10.1111/j.1365-2133.2012.10830.x [published Online First: 2012/01/19]



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44. Bath-Hextall F, Nalubega S, Evans C. The needs and experiences of patients with skin cancer: a qualitative systematic review with metasynthesis. *Br J Dermatol* 2017;177(3):666-87. doi: 10.1111/bjd.15148 [published Online First: 2016/10/25]
45. van Egmond S, Wakkee M, Droger M, et al. Needs and preferences of patients regarding basal cell carcinoma and cutaneous squamous cell carcinoma care: a qualitative focus group study. *Br J Dermatol* 2018 doi: 10.1111/bjd.16900 [published Online First: 2018/06/22]
46. Wammes JJ, Jeurissen PP, Verhoef LM, et al. Is the role as gatekeeper still feasible? A survey among Dutch general practitioners. *Fam Pract* 2014;31(5):538-44. doi: cmu046 [pii]

10.1093/fampra/cmu046 [published Online First: 2014/08/20]
47. Westert GP, Jeurissen PPT, Assendelft WJJ. Why Dutch general practitioners do not put the squeeze on access to hospital care? *Family Practice* 2014;31(5):499-501.
48. Rotar AM, Van Den Berg MJ, Schafer W, et al. Shared decision making between patient and GP about referrals from primary care: Does gatekeeping make a difference? *PLoS One* 2018;13(6):e0198729. doi: 10.1371/journal.pone.0198729

PONE-D-17-43535 [pii] [published Online First: 2018/06/12]
49. Bluestone J, Johnson P, Fullerton J, et al. Effective in-service training design and delivery: evidence from an integrative literature review. *Human Resources for Health* 2013;11(1):51. doi: 10.1186/1478-4491-11-51
50. Lugtenberg M, Pasveer D, van der Weijden T, et al. Exposure to and experiences with a computerized decision support intervention in primary care: results from a process evaluation. *BMC Fam Pract* 2015;16:141. doi: 10.1186/s12875-015-0364-0

10.1186/s12875-015-0364-0 [pii] [published Online First: 2015/10/18]
51. Grol R, Grimshaw J. From best evidence to best practice: effective implementation of change in patients' care. *Lancet* 2003;362(9391):1225-30. doi: S0140-6736(03)14546-1 [pii]

10.1016/S0140-6736(03)14546-1 [published Online First: 2003/10/22]
52. Grol R, Wensing M. What drives change? Barriers to and incentives for achieving evidence-based practice. *Med J Aust* 2004;180(6 Suppl):S57-60. doi: gro10753_fm [pii] [published Online First: 2004/03/12]

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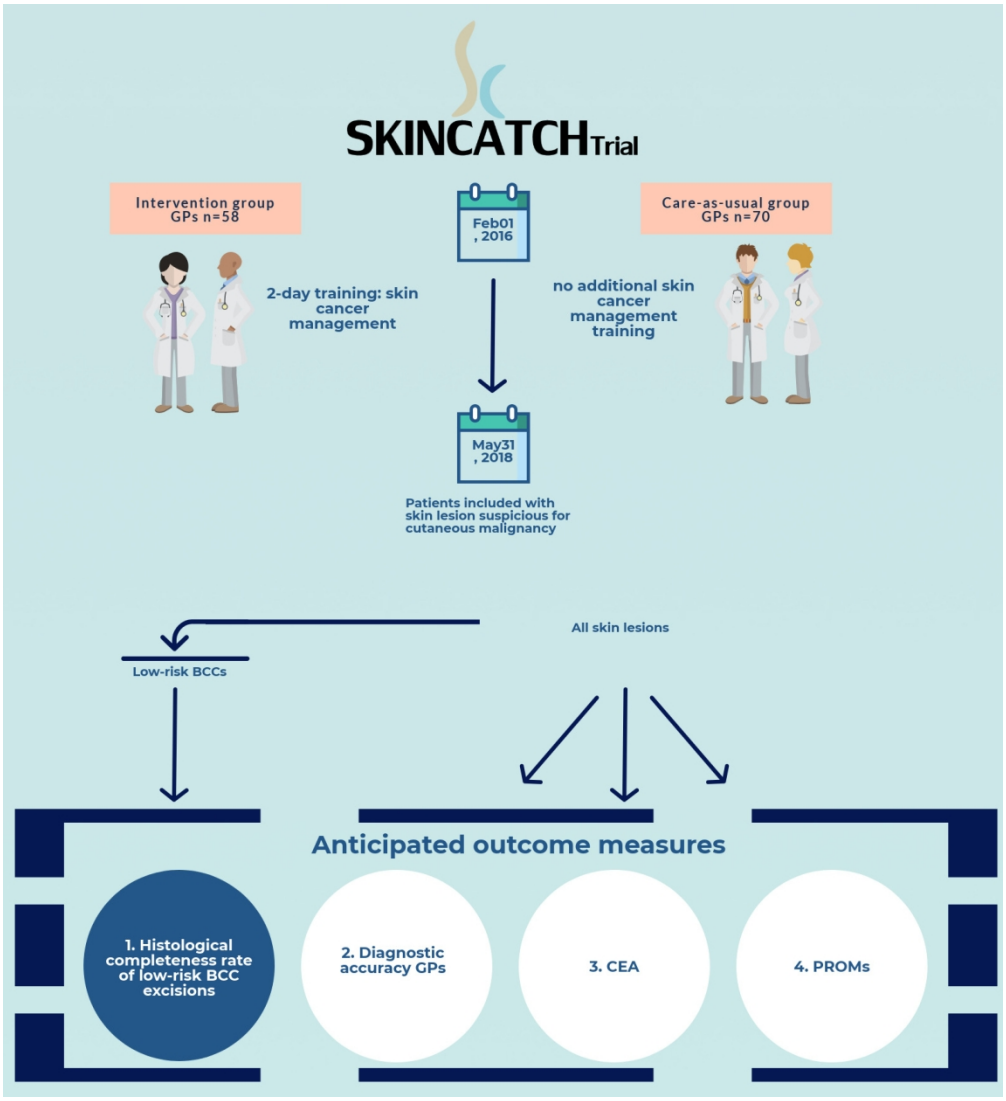


Design SKINCATCH Trial

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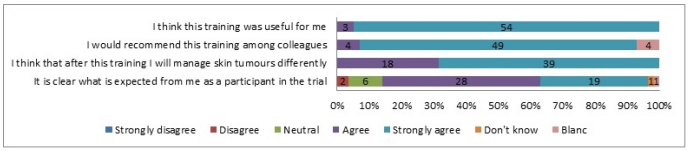


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# Supplementary material

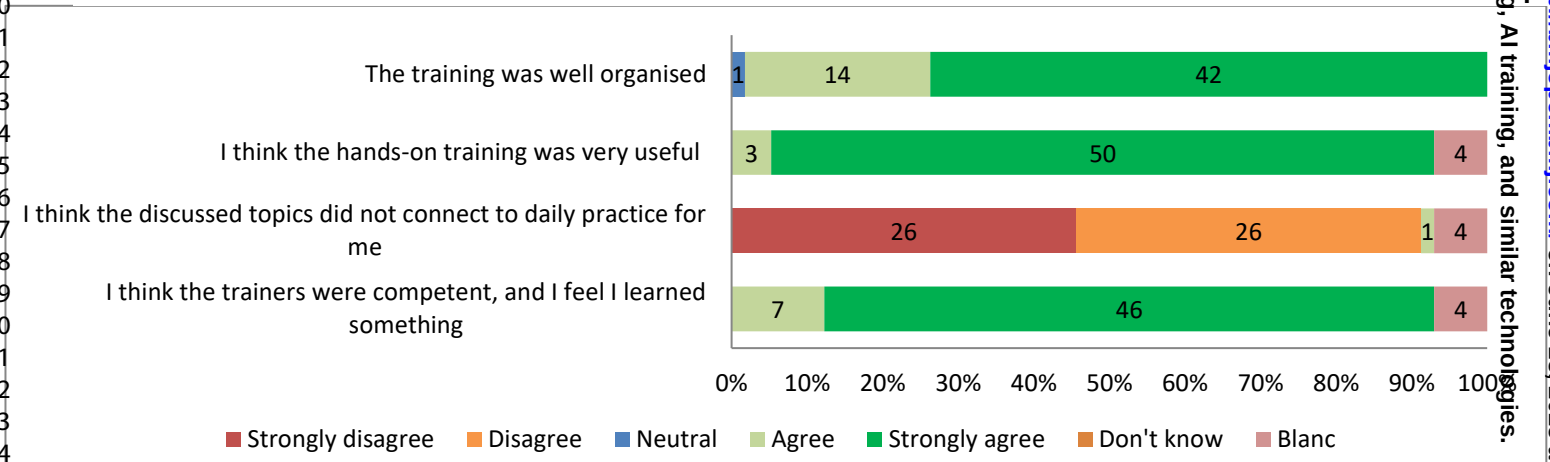
## Supplementary tables

**Table S1: Characteristics of GPs participating in the focus group meetings.**

| | Focus group 1 | Focus group 2 | Focus group 3 | Total |
|---|---|---|---|---|
| Total, n | 8 | 5 | 4 | 17 |
| | | | | |
| Intervention group, n(%) | 4 (50) | 2 (40) | 3 (75) | 9 (53) |
| Male, n(%) | 4 (50) | 2 (40) | 1 (25) | 7 (41) |
| Age, median (IQR) | 51 (43-57) | 49 (41-62) | 36 (35-52) | 49 (39-57) |
| Years of professional experience, median (IQR) | 17 (12-22) | 16 (7-30) | 8 (7-25) | 14 (8-25) |
| Professional environment, n(%) | | | | |
| Individual practice | 2 (25) | 1 (20) | 0 (0) | 3 (18) |
| Duo practice | 2 (25) | 3 (60) | 2 (50) | 7 (41) |
| Group practice or medical centre | 4 (50) | 1 (20) | 2 (50) | 7 (41) |
| | | | | |
| *Abbreviations: GP, general practitioner; IQR, interquartile range* | | | | |

## Supplementary figures

**Figure S1: Additional outcomes of the training evaluation survey.**

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# Appendices

## Appendix A

Training evaluation survey February 2016.

| Statement | Strongly disagree | Disagree | Neither agree or | Agree | Strongly agree | Don't know | No opinion | Not filled in |
|---|---|---|---|---|---|---|---|---|
| 1.I would recommend this training for my colleagues. | | | | | | | | |
| 2. The hands-on part using human specimen was useful. | | | | | | | | |
| 3. The subjects of the training did not reflect daily practice. | | | | | | | | |
| 4. The teachers were competent, I learned something today. | | | | | | | | |
| 5. The training was well organised. | | | | | | | | |
| 6. It was clear was it expected from me as a participant in the trial. | | | | | | | | |
| 7. After this training, I will manage patients with skin cancer differently. | | | | | | | | |
| 8. This training was useful for me. | | | | | | | | |

## Appendix B

Trial evaluation survey November 2016.

Q1: In which study group are you randomized?

a. Intervention group
b. Care as usual group

Q2: How many patients did you include in the trial? ….

Q3: Statement; I do see patients with cutaneous lesions suspicious for a malignancy. The reason I do not include them in the trial are…

a. Lack of time
b. I don't understand the study forms
c. The trial restricts me in skin cancer excisions
d. I am afraid to do skin surgery
e. The patients declined
f. Financial reasons
g. I realize I could have included patients afterwards
h. I don't want to include patient because then I have to treat them differently
i. Other: ….

Q4: Numbers show that GPs should see around 5 patient a year who meet the criteria for low-risk basal cell carcinomas (i.e., <1cm, non-aggressive subtype, primary tumour, low-risk locations).

a. I see less than 5 patients
b. I see 5 patients, but I don't include them



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c. I see more than 5, but I don't include them
d. Other: ….

Q5: Statement; it would be easier for me to only include patients with a skin lesion suspected for low-risk basal cell carcinoma, instead of patient with a skin lesion suspected for a malignancy in general.

a. Agree
b. Disagree
c. It does not matter

Q6: How often would you like to be reminded by us for including patients in the trial?

a. Weekly
b. 2-weekly
c. Monthly
d. Other: ….

Q7: Do you think it would be easier to include patients if these consultation were clustered?

a. Yes
b. No

Q8: Do you have any ideas how we can make it more easy for you? All ideas are welcome! …

Q9: Do you have any final remarks? …

## Appendix C

Medical record analysis.

| Selected ICPC codes | |
|---|---|
| S04 | Localised tumour skin/subcutis |
| S05 | Multiple tumours skin/subcutis |
| S06 | Localised redness/erythema of the skin |
| S21 | .01 Dry skin/ squamae<br>.02 Lichenification/induration |
| S26 | Fear for cancer of the skin/subcutis |
| S77 | .01 Basal cell carcinoma<br>.02 Squamous cell carcinoma<br>.03 Malignant melanoma<br>.04 Kaposi sarcoma |
| S79 | .01 Dermatofibroma |
| S80 | .01 Dysplastic naevus |
| S82 | Naevus/mole |
| S99 | .01 Granuloma pyogenicum<br>.02 Seborrheic keratosis<br>.03 Rosacea<br>.04 Vitiligo<br>.05 Discoid lupus erythematosus<br>.06 Lichen planus<br>.07 Striae |



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| | |
|---|---|
| | .08 Erythema nodosum<br>.09 Keloid<br>.10 Keratoacanthoma<br>.11 Actinic keratosis |

## Appendix D

**Introduction**

- Introduction
- Background and aim of study
- Aim and structure of interview
- Informed consent forms, permission audio-taping, demographic questionnaire to be filled in
-

**Part 1: Experiences with the SKINCATCH Trial**

- General experiences with the trial

**Part 2: Perceived barriers related to the low inclusion rate**

- Perceived barriers related to the low inclusion rate of low-risk BCCs in the trial

**Part 3: Perceived barriers related to the implementation of the trial (low excision rate)**

- Perceived barriers related to the low excision rate

**Part 4: Suggestions to facilitate implementation in the future**

- Practical solutions to facilitate implementation

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