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Asplenic patients' and doctors' experiences in implementing preventative measures following a novel educational intervention: a qualitative analysis

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ABSTRACT

Objective: To explore asplenic patients' and GPs' (1) perceptions of a novel, *Health Action Process Approach* (HAPA)-based, educational intervention which targets to increase adherence to post-splenectomy sepsis (PSS) prevention measures and (2) their experience in implementing prevention measures following this intervention.

Design: A process evaluation conducted on average 3.5 (for patients) and 3.8 (for GPs) months after the intervention between January 2020 and April 2021 individually by means of semi-structured guideline-based telephone-interviews. Data was analysed using qualitative content analysis.

Participants: Volunteer sub-sample of N = 25 asplenic patients and N = 8 GPs who received the intervention. Inclusion criteria were met by prior participation in the intervention (German-speaking, of full age and insured by the cooperating health insurance). Patient selection was done by purposeful selection aiming at maximum variability in terms of adherence to preventative measures prior to intervention participation. Participating GPs are a non-purposeful selected convenience sample. For reasons of data protection, no personal data was collected.

Results: The intervention was positively evaluated and its personal relevancy for patients and for the GPs' professional work became apparent. The intervention promoted risk awareness, intention to action, action planning and subsequently, improved adherence to preventative measures. Helpful factors for implementation among the patients were social support by relatives and GPs. Barriers to adherence identified in both groups can be divided into patient-attributed (e.g. comorbidities), doctor-related (e.g. lack of knowledge or support) as well as contextual factors (e.g. vaccine supply constraints).

Conclusions: Our findings indicate a patient and GP perceived benefit of the intervention, but still identify prevailing barriers to implementation. In a further step, a quantitative evaluation of the intervention will be conducted and recommendations for integrating the intervention in usual care will be made.

Trial registration: German Clinical Trials Register (DRKS): DRKS00015238; Trial registration date is 7th December 2018.

Keywords: Asplenia, Post-splenectomy sepsis (PSS), Sepsis, Splenectomy, General practitioners (GPs), Prevention, Intervention, Health Action Process Approach (HAPA), Interviews, Qualitative Content Analysis, Barriers

Article Summary

Strengths and limitations of this study

- This is the first study in the field of asplenia that explores in depth patients' and GPs' experiences in implementation of PSS preventative measures following an intervention intended to increase adherence.
- Purposeful selection of patients which aimed at maximum variation regarding their pre-interventional adherence enabled to explore a sample with diverse initial experiences in preventative behaviour.
- A minor limitation as regards to the intended maximum variation selection is that very high levels of adherence did not occur in the sample.
- Since participation in the interview, which serves as the data basis in this study, was a voluntary additional effort, a positive bias might have been induced.

INTRODUCTION

Patients with an absent or dysfunctional spleen are susceptible to infectious diseases throughout their lives and are at an increased risk of developing an post-splenectomy sepsis (PSS; also called overwhelming post-splenectomy infection, abbr. OPSI)[1], with a mortality rate up to 50%[2]. According to international clinical guidelines, OPSI is largely preventable through prophylactic measures in this patient population[3]. These measures include amongst others anti-pneumococcal and anti-meningococcal vaccination, permanent availability of a medical alert card and an antibiotic supply for emergency fever treatment ('pill in the pocket') as well as patient education.

However, there is widespread evidence, that guideline awareness and adherence are low[1]. Even if the doctor's knowledge and attitude towards guidelines was found to be appropriate, patient education by health providers as well as inter-sectorial communication were described as insufficient[4]. Thus, many asplenic patients have poor knowledge about the risk associated with their condition and existing prevention recommendations[i.a. 5-7]. Beyond these knowledge (transfer) gaps mainly reported in literature, barriers such as safety concerns, scepticism and the doubted need for vaccination are further reasons that were found for asplenic patients' non-adherence[8]. As better patient knowledge can be considered a key factor in improving adherence[9], and primary care providers are critical in patient education and prevention implementation[8, 10], we developed a novel educational intervention for both asplenic patients and for their general practitioners (GPs) (for a detailed description of the intervention see[11] or supplemental material).

The intervention is a manual-based individualised telephone counselling on evidence-based information of the spleen, asplenia-related infection risks and infection prevention recommendations, conducted by an infectious diseases specialist. The *Health Action Process Approach* (HAPA), a framework that provides predictors for initiation and maintenance of preventative behaviour[12], including vaccination behaviour[i.a. 13], served as theoretical basis. Distinguished into two phases in the HAPA, these predictors include risk perception, outcome expectancies and perceived task self-efficacy which influence the formation of an

intention (*motivational phase*) as well as action and barrier coping planning and maintenance self-efficacy that lead to the actual behaviour (*volitional phase*). Accordingly, our intervention includes specific components which promote motivation for initiation as well as action-related strategies such as planning and managing barriers, the latter being realised through a customisable action plan for patients. For doctors, the intervention is primarily information-orientated by conveying current guideline recommendations for asplenic patients in general and the attending patient specifically. Accompanying the telephone intervention, participants receive written information tailored both to patient and doctor, along with a plain vaccination schedule and a medical alert card.

The intervention is currently being evaluated in terms of its effectiveness in a two-armed historical control-group design. Moreover, as recommended for complex interventions[14], the intervention was evaluated in a qualitative process evaluation. The findings of the process evaluation will be reported in the present article, the quantitative findings will be reported elsewhere. The aim of the process evaluation is to investigate how patients and doctors evaluate the intervention and how they perceive its usefulness for implementation, with particular attention to health behaviour changing factors according to HAPA. And notably, the objective is to gain a deeper understanding of the participants' experience in implementing the preventative measures post-intervention, including factors that influence adherence, that are subjectively perceived barriers as well as helpful factors.

METHODS

Study design

This is a qualitative interview-study conducted with asplenic patients and attending GPs. The methods are presented in accordance with the consolidated criteria for reporting qualitative research (COREQ) checklist[15] (see supplemental material).

Patient and public involvement

Patients or the public were not actively involved in this research.

Participants and recruiting

The sample is a sub-sample of asplenic patient and doctor participants, who received the intervention and were willing to take part in an additional interview (willingness was queried after participation in the intervention on the phone). Inclusion criteria for patients were met by prior study participation (these were German-speaking, of full age and insured by the cooperating AOK health insurance; see[11]). All interviewees provided written informed consent to participate, including having their interview audiotaped and further processed. They received a 30 € voucher for participation. For reasons of data protection, no personal data was collected.

Patient participants

Patients were selected using a maximum variation sampling approach (purposeful sampling). A maximum variability in terms of their pre-interventional study-specific 'Preventing PSS-score' ('PrePSS-score') was sought. The 'PrePSS-score' indicates patients' adherence to the recommended preventative measures on a scale from 0 to 10 (anti-pneumococcal and anti-meningococcal vaccination, availability of a medical alert card and of an antibiotic supply; for details on development and calculation of the 'PrePSS-score' see[11]), with higher scores indicating greater adherence. With this approach, we expected to explore diverse experiences in implementation as those might differ according to prevention measures taken prior to the study participation.

Selection was performed in two phases. Firstly, all the patients who had agreed to participate were selected successively. After conducting initial N=14 interviews, further patients were purposively selected in an iterative process on the basis of so far unrepresented or underrepresented preinterventional 'PrePSS-score' to obtain maximum variation. Appropriate maximisation was assumed when each possible 'PrePSS-score' (0-10) occurred at least twice. Thus, this approach was also used to determine the minimum number of interviews necessary. Since the values 7, 9 and 10 did not occur among patients who were willing to participate, the range of variation was determined by the actual scores present for this sub-group (for exact frequencies see table 1).

In total N=31 patients were contacted. As N=6 of them did not provide written consent (N=1 refused participation due to ongoing treatment, N=5 could not be reached), N=25 patients were interviewed. That is 22.7% of all patients (N=110) who received the intervention.

Table 1 *Frequencies of the preinterventional 'PrePSS-score' of the participants*

PrePSS-score (0-10)	**N**	**%**
0	1	4
1	4	16
2	5	20
3	3	12
4	4	16
5	3	12
6	3	12
7	0	0
8	2	8
9	0	0
10	0	0

Doctor participants

Due to low participation willingness and difficulties with accessibility (presumably in part because this study was conducted during the COVID-19-pandemic) a non-purposeful selection

procedure was required for the doctors. We took a convenience sample of doctors, i.e. all those who were willing to participate (N=11) were contacted for study participation. Among these, N=8 participated. The remaining N=3 participants were not reachable (N=2) or refused participation due to lack of time (N=1). Participating doctors were the GPs of any of the intervention group patients. Thus, patients and doctors were not chosen in pairs for the interviews.

Interview guideline

The semi-structured interview guidelines for patients and doctors were drafted by N.A und M.B. following Helfferich (2011)[16] and finalised after review by the whole study team. Marginal adjustments to improve applicability were made upon mutual agreement between the interviewers after 14 patient interviews were conducted.

The interview guide for patients was divided into three obligatory main blocks on the topics (a) ′evaluation of the telephone intervention′ (initial question), (b) ′experience in implementing preventative measures′ and (c) ′dealing with sepsis risk′ and (d) a supplementary block addressing the written information material accompanying the telephone intervention. Each question block contained an open-ended obligatory core question that subsumed the key aspects of each topic. Interviewees were to be given the opportunity to freely report on their experiences, specific questions were only posed if a relevant aspect of the core topic was not proposed by the participants. The interview guide for doctors contained the topics (a) ′evaluation of telephone intervention′ (initial question), (b) ′usefulness of the telephone intervention′ and (c) a question block addressing the written information material. Overall, the doctor interview guide was more information-orientated compared to the patients' guide, and improvement suggestions were directly requested from doctors. The interview guidelines are attached as supplementary table 1 and 2.

Procedure and transcription

Patients and doctors were interviewed individually between January 2020 and April 2021 via telephone by M.B. and N.A. using the developed guideline. M.B. and N.A., both female research assistants and psychologists with experience in counselling and conversation techniques were responsible for the development of the guidelines and the implementation and analysis of the interviews. They were also involved in the development of the manuals for the patient and doctor-directed interventions. Apart from a short telephone contact to arrange the interview date, the interviewers did not know the interviewees beforehand. They introduced themselves as part of the study team responsible for evaluating the intervention. Participants were informed that the study-doctor who conducted the telephone intervention would have no access to recordings or transcripts of individual patient interviews, but only to aggregated, pre-processed data of all the interviewees.

The interview dates were scheduled about 3 months after the telephone intervention. For practical reasons, this period between the intervention and the interview varied between 2.5 and 6.5 months (on average 3.5 months) among the patients. For the doctors, the time period varied between 2.5 and 7.3 months (on average 3.8 months). All interviews were digitally audio-taped in full. No field notes were taken during the interview. The audio recordings were transcribed verbatim by an external transcription service provider. Personal data were pseudonymised before data analysis. Neither transcripts nor results were returned to participants for feedback.

Data analysis

The transcripts of the interviews were analysed using qualitative content analysis largely based on the approach of Kuckartz (2018)[17], which involves both deductive and inductive coding. The chosen multi-level procedure for this study is outlined in Table 2.

Table 2 *Levels of the qualitative content analysis*

Familiarisation stage	Before coding, the entire transcribed text material was read intensively in the process of pseudonymisation and short case summaries were composed.
Inductive-deductive development of the initial coding frame	Based on this familiarisation stage, codes were extracted inductively by N.A. In a next step, additional codes were derived deductively from key topics of the interview guideline, from previous research on barriers that influence patients' adherence to preventative measures [18] and from the underlying theoretical HAPA.
Quota sample trial phase and revision	This initial coding frame was then applied to a quota sample consisting of 20% of the data material (N=5 patient and N=2 doctor interview transcripts), comprising interviews from both interviewers collected at various time points during data collection. In the process of this trial phase, the codes were refined several times through continuous reflection and classified into main and sub-codes.
Entire data material trial phase and team-review	This was followed by the first coding of the entire data material along the so far defined coding frame. In this process, codes were again revised if required, e.g. summarised or differentiated into further sub-codes. In this process a coding guideline was formulated. To ensure intersubjective comprehensibility, the coding frame, the guideline and the coding of individual, randomly chosen interviews were critically reviewed by M.B., M.G. and E.F. and, if needed, slightly adapted to their feedback. This resulted in the final set of six main codes and 11 sub-codes for patients and four main codes and four sub-codes for doctors (for an overview see table 3 and 4).
Application of the final coding system	This final coding system was then applied to the entire data material by N.A.
Extraction of a code x participant-summary-matrix	In the last step, all the statements of a participant assigned to the same code were paraphrased and the overall findings were extracted from a code x participant-summary-matrix.

Data organisation and analysis was performed using MAXQDA Plus 2020 (version 20.0.3) qualitative data analysis software. Following quantitative descriptive information was calculated using IBM SPSS Statistics (version 27). The entire patient data material to be analysed had covered a duration of about 712 minutes, the data material of doctors circa 148 minutes. The patient interviews lasted between 9 and 75 minutes, with an average length of

28 minutes; doctor interviews lasted between 7 and 30 minutes, on average 18 minutes. The interviews were conducted in German. Code descriptions and quotations taken from the interview transcripts given below are translations from German into English.

Table 3 *Final coding system of patients' interviews*

Main codes	**Sub-codes**
Implementation of preventative measures	
Barriers to implementation of preventative measures	
Perceptions of the intervention	*Evaluation of the telephone intervention and accompanying information material*
	Personal relevance of the intervention
Perceived impact and usefulness of the intervention for implementation	*Implementation of preventative measures*
	Motivation for implementation
	Initiation and maintenance of steps necessary for implementation
	Initiation and maintenance of implementation through prior planning
	Perceived effects of the intervention on the GP
Infection-related risk perception following the intervention	*Cognitive-affective level*
	Behavioural level
Barriers and helpful factors for implementation of preventative measures following the intervention	*Barriers to implementation*
	Helpful factors: social support

Table 4 *Final coding system of doctors' interviews*

Main codes	Sub-codes
Barriers to implementation of preventative measures	
Perceptions of the intervention	*Evaluation of the telephone intervention and accompanying information material*
	Relevance of the intervention for own professional work
Perceived impact and usefulness of the intervention for implementation	*Implementation of preventative measures*
	Perceived impact on further medical action
Barriers to implementation of preventative measures following the intervention	

FINDINGS

Patients' interviews

Implementation of preventative measures

Only few patients made reference to prevention measures that had been implemented prior to study participation, with most of them indicating initial approaches and none the full implementation of recommendations. Patients reported having already received (some or all of) the recommended initial vaccinations. These vaccinations had been administered post-splenectomy by the hospital conducting the splenectomy, after discharge by the GP, a specialist or during rehab and, in two cases of elective surgery, even before the splenectomy. Furthermore, a few patients stated that they had already received a medical alert card for asplenic patients from hospital, which, however in some cases were not filled out completely or not permanently available.

Barriers to implementation of preventative measures

Regarding barriers to implement preventative measures, personal, contextual, as well as doctor-attributed factors could be found. The majority of patients mentioned their own insufficient or complete lack of knowledge about the infection risk associated with asplenia and (the need for) corresponding preventative measures. Poor relevant knowledge and failures in implementation were largely attributed to the GP, to the hospital or the rehab centre (or their cooperation), with patients stating that they were either inadequately, incorrectly, incomprehensibly or not at all educated and patients assumed that a lack of relevant knowledge, time or priority by the health care providers were the reasons.

'However, the hospital staff said that everything was okay and that it was possible to live without a spleen.' [ID020314]

Furthermore, comorbidity (mostly cancer) and/or the poor health condition of patients influenced measure implementation as disease-related fears and treatments gave less priority to vaccinations necessitated by the splenectomy or were the reason for their temporary contraindication. Contextual barriers included vaccine supply difficulties and vaccine costs considered not being borne by the health insurance. The results presented below refer to the intervention and to experiences following the intervention.

Perceptions of the intervention

Evaluation of the telephone intervention and accompanying information material

As regards the evaluation of the telephone intervention, a relatively homogeneous picture emerged. Respondents experienced it as pleasant, patient-centred and some mentioned they felt taken care of. The information provided was evaluated as being informative and comprehensible (except for some of the technical terms and abbreviations used). Duration was deemed appropriate and necessary. As to the information material, patients stated they made use of it and some kept it to be able to refer to it at any time. It was rated as informative (in particular the vaccination schedule included) and comprehensible. However, some people clearly expressed the added value of the telephone intervention aligned to the written

information material over only having the information material, especially when considering comprehension.

Personal relevance of the intervention

Beyond the evaluation of the intervention, its personal relevancy for the participating patients became apparent. Interviewees were appreciative of having received previously unknown or incomplete disease-specific information they rated as subjectively important. They stated that their awareness of risk factors and necessary prevention was formed or increased by the (new) information and some reported they felt safer having been educated now.

'And I have to say, it has also given me a sense of security. And the education was very good, because, as I said before, I had no idea […]' [021310]

Impact and usefulness of the intervention for implementation

Implementation of preventative measures

All the respondents who provided information on immunisation had received the recommended vaccinations since the telephone intervention or had already planned outstanding (or booster) vaccinations. The medical alert card and the antibiotics for emergency treatment were also mostly permanently available to patients (left in the car, handbag, wallet or mobile phone case), even though there were some failures in filling the alert card in.

Motivation for implementation

Some participants explicitly expressed that the intervention had nudged them to plan, implement or adhere to preventative measures or to demand implementation from their GP.

'[…] that the thought process started for me, what do I have to pay attention to for myself? What do I need to make my general practitioner aware of?' [ID090709]

Aside from that, three interviewees made reference to the influenza vaccination, which they had never received before, but were convinced of its necessity due to the telephone consultation.

Initiation and maintenance of steps necessary for implementation

A large proportion of patients said that they had seen their GP following the telephone intervention to inform him or her of their participation in the study, of required preventative measures and to demand their implementation. Among other things, patients themselves (co-)monitored and organised vaccine supply, vaccination dates and sequence and some partially filled in the medical alert card. In order to keep track of vaccination boosters and expiration dates of the antibiotics, some reported making use of calendar reminders or other notes.

Initiation and maintenance of implementation through prior planning

Some interviewees stated that they followed the individual action plan they had established during the telephone intervention prompted by the study doctor and that they made use of the corresponding worksheet to monitor implemented and pending preventative measures.

Perceived effects of the intervention on the GP

During a consultation following the telephone intervention, patients reported that they perceived their GPs being open to the (new) information and to study (participation). Preventative measures would have taken an unprecedented priority as most doctors supported the implementation by initiating or monitoring the process (e.g. deposited study information, arranged vaccine supplies, reminders about (booster) vaccinations, or completion of the medical alert card).

'So, I have the impression that he's already got this properly on the agenda, to pursue it now and also to take it further. […]. And I attribute this to the conversation with you.' [ID090709]

It has to be mentioned here, that, to the patient's knowledge, some of the GPs had received the telephone intervention for doctors at the time of the patient interview and others had not (yet).

Infection-related risk perception following the intervention

Cognitive-affective level

Some patients indicated that they had (initially) been alarmed, concerned or anxious when receiving (largely) unfamiliar information on the asplenia-related infection and sepsis risk through the intervention. Some described being uncertain about potential risk factors and signs of sepsis as well as about whether they, in case of infection, would react properly. There were also patients who were quite optimistic and unconcerned. Some of these (as well as some of those who stated they were initially concerned) said that they felt safe and prepared to deal with the existing risk thanks to comprehensive education, as well as through preventative measures (to be) taken and knowledge of their efficacy.

'Because before that, it was rather in abeyance. I just read and heard: Yes, blood poisoning, far, far greater risk. […]. However, after that [telephone intervention] it was a bit better […]. So, I don't imagine now my hand suddenly falling off from one second to the next.' [ID021012]

Behavioural level

Besides the cognitive and affective consequences of risk perception, respondents also adapted their behaviour following the intervention. Beyond implementation of the main preventative measures, patients showed precautionary behaviour (i.e. avoiding crowds, keeping their distance from potentially sick people, wearing face masks, being careful about hand-hygiene, avoiding injuries and if needed seeing a doctor sooner) or were alert for symptoms. Some interviewees made direct reference to the current COVID-19-pandemic, which probably had enhanced or induced caution.

'I'm also paying more attention to myself now, even more. And I check every day, is there anything that doesn't belong there? This line or am I warm and have high temperature, […].' [ID120714]

Barriers and helpful factors for implementation following the intervention

Barriers to implementation

For implementation of the targeted preventative measures following the intervention, again personal, contextual as well as doctor-attributed barriers were depicted. The most common personal reason for delayed or prolonged implementation of (booster) inoculations was comorbidity (ongoing chemotherapy or immune treatment), less often mentioned was the personal refusal of the influenza vaccination. Doctor-attributed barriers were poor support in initiating and administering vaccinations, inadequate education about side effects by or confusion about the vaccination sequence. Other barriers were vaccine supply shortages, difficulties in appointment availability and coordination and, in one case, vaccination costs that were assumed to not be covered by the health insurance. Concerning the medical alert card, a few interviewees stated that they were not able to complete it themselves, with some GPs refusing to help. One patient expressed discomfort at having to manage and carry several (vaccination attesting) documents.

'What I found a pity was that I often presented the medical alert card to my doctor, to my family doctor, but they didn't want it at all... in fact, they didn't even look at it.' [ID041710]

Reasons for not having antibiotics available for emergency treatment were lacking (patient or doctor) conviction or knowledge of individual need, as well as lack of cooperation of the GP. In another case, a patient criticised that her GP did not educate her about the use (including dosage) of the prescribed antibiotic.

Helpful factors: social support

A good relationship, experienced general support, as well as professional advice and care by the GP (and the GP co-workers) were mentioned as a helpful factor in prevention implementation and in coping with their condition by many interviewees. Among other things, it seemed to be of great significance for patients to be able to rely on their GP for (prospective) measure implementation. A large proportion also felt supported emotionally and in prevention implementation by their relatives (thanks to accompaniment to doctor's appointments, for

example). Some subjects actively involved family members (in one case also colleagues) by informing them about the disease specifics and preventative measures necessary or already taken (e.g. depository of emergency antibiotic supply).

Doctors' views

Barriers to implementation of preventative measures

For implementation of the preventative measures prior to study participation, interviewed doctors mentioned both doctor (i.e. own) and health care system-related barriers as well as patient-attributed barriers. Most notably, interviewees described own knowledge gaps or uncertainties when it comes to asplenia-specific risks, updated vaccination recommendations or the necessity of an antibiotic prophylaxis and some made reference to their minimal routine in the treatment of this patient group. Furthermore, two doctors described deficits at the hospital-outpatient care interface, on the part of the hospital (e.g. misleading information in the discharge letter, lack of raising patients awareness of further out-patient care by GP) as well as the own lack of awareness and assumed patient's failures.

'And that is my mistake, the patient´s mistake, and at the same time the [name of hospital]´s mistake is also present, a hundred percent. All the stops have not been pulled out properly.' [ID072212]

Perceptions of the intervention

Evaluation of the telephone intervention and accompanying information material

The intervention was overall positively evaluated by all the GPs interviewed. The telephone based intervention was viewed as pleasant, instructive and individually-adapted to prior knowledge and the attending patient. The duration of the phone call was viewed as appropriate. Accompanying information material was mostly used and/or deposited for future recourse, content was evaluated as helpful and the scope (with one exception) as adequate. Still, all the GPs gave preference to the telephone consulting over only written information material (in terms of raising awareness and the opportunity to discuss aspects in depth).

Relevance of the intervention for own professional work

Beyond formal evaluation, the GPs addressed the effect of the intervention for their work. They stated that they received subjectively new or up-dated information on asplenic preventative care, classified as reliable (expert knowledge) and helpful for the treatment of their patients. Besides knowledge (-reactivation), they mentioned increased attention to their (further) patients affected and their own responsibility in implementing and monitoring (e.g. when it comes to booster vaccinations, periodic renewal of antibiotic prescriptions) the precautions.

'So we already knew what we had to do in case of asplenia, but we still hadn't had it on our minds that much.' [ID042812]

Impact and usefulness of the intervention for implementation

Implementation of preventative measures

GPs mentioned preventative measures already implemented or ongoing, mostly in terms of vaccinations. Since the systematic record of their factual implementation was not the aim of this interviews, but rather the experience of it, corresponding responses remained quite vague and rare.

Perceived impact on further medical action

Besides implementation of the measures themselves, GPs also named heterogeneous other consequences for their work. For instance, adaption of vaccination schedules and templates for doctor´s letters, storing of patients' asplenia-specific information in the internal system, targeted summoning and broader education of affected patients as well as a more extensive diagnostic work-up in the case of infections.

Barriers to implementation of preventative measures following the intervention

As regards the implementation of the preventative measures following the intervention, doctors (i.e. own), health care system-related and patient-attributed barriers as well as contextual factors were described by interviewed GPs. Doctor-attributed barriers to vaccination were lack of clarity in the case of concurrent other treatment (e.g. chemotherapy) and inconsistencies in

the vaccination sequence originating from the hospital. At the patient level, comorbid diseases and poor health as well as associated uncertainties posed an obstacle (e.g. refusing immunisation during chemotherapy out of fear). Furthermore, GPs stated vaccination delays due to delivery constraints and named an extra effort of parallel vaccination documentation (medical alert card for asplenia and vaccination certificate).

DISCUSSION

This study explored asplenic patients' and GPs' perceptions of a novel intervention aiming to increase adherence to PSS prevention measures and their experiences in implementation following this intervention by means of a process evaluation. The results of both participant groups provide a relatively homogenous picture and will be discussed conjointly in the following.

The intervention was overall positively evaluated by both patients and GPs. This referred to the intervention framework, comprehensiveness and informative value as well as to its recipient-centeredness, with the telephone based part of the intervention outweighing the written information material provided. Furthermore, the intervention seemed to have a great personal relevance for patients and for the attending doctors' professional work. Both groups reported newly emerged or increased subjective relevant knowledge. This was linked to a sense of security of being well informed in one´s own matter on the part of the patients while GPs mentioned an increased sense of responsibility in the implementation of precautions and several practical implications in the asplenic patients' management.

Even though barriers to initial adherence were not an intended focus of the interviews, most participants referred to it. Both similarities and deviations from relevant studies could be found. Corresponding to previously reported studies, poor relevant patient knowledge were found[4, 5, 7]. Furthermore, comorbid diseases influenced feasibility of the measures, as well as deficits in inter-sectorial communication, the latter also being identified as a key barrier for doctor guideline-conform patient management[4]. However, in comparison to DiSabatino et al. (2017)[8], who described asplenic patients' concerns about the safety of vaccination or scepticism about its benefits as barriers to vaccine prophylaxis, these aspects were not detectable in our interviews.

The intervention, which was theoretically based on the HAPA[12], seemed to be an appropriate strategy to promote asplenic patients' intention to action, action planning and subsequently, to improve adherence to prevention measures. Patients portended they developed risk awareness, were convinced, and felt motivated and empowered to plan and implement

preventative measures or demand their initiation from their GPs. It can be suggested that patients demonstrated self-management behaviour, they presumably did not show before. Risk awareness was manifested on the cognitive-affective level with a tendency of increased anxiousness and mental preoccupation or realistic risk estimation and self-efficacy, as well as in increased health precautionary behaviour and alertness for infection symptoms. Overall, the results indicate that the targeted prevention measures were mostly implemented appropriately and in full following the intervention. Subject to the pending quantitative evaluation, we thus have initial indications that our findings fit in with other research showing the feasibility of HAPA-based interventions in the context of prevention behaviour[i.a. 13].

Our results depict helpful factors and barriers to implementation. As far as helpful factors are concerned, patients alluded to the social support of their GPs, as well as through relatives. Patient and GP reported barriers can be divided into patient-attributed, doctor and contextual or health care system-related factors. Reasons for prolonged or missed vaccination were comorbidities and related treatments (e.g. chemotherapy) and, very rarely addressed, a patient´s personal refusal. Lack of knowledge, support and education on the part of the GPs were also negatively contributing factors. Other reasons were at a contextual level, e.g. vaccine supply constraints, lack of appointment availability or, brought in by GPs, cooperation deficits between hospital and out-patient care. Since the intervention aimed to address evidenced barriers, it corresponds with the expectation that in the overall picture, these were disease-related or structurally given barriers, which could not be addressed by the intervention (e.g. vaccine availability), that would emerge.

The interpretation of all the results must be done bearing in mind that selection bias cannot be ruled out. As participation in the interviews was a voluntary additional effort, participating patients and GPs might be a certain subgroup of study participants who tend to be motivated or in favour of the intervention and thus may have induced a positive bias in terms of intervention evaluation and reported implementation. Furthermore, selection might have influenced patient-reported barriers (e.g. mostly action-related, rather than personal attitudes opposing prevention measures). Although the patient selection was purposefully aiming at

maximum variation regarding their pre-interventional adherence ('PrePSS-score'), it must be further mentioned that very high levels of the PrePSS-score did not occur at all in the sample. However, we argue that this is less severe, as it represents exactly those patients who are the target group of our intervention, as the intervention is not urgent for patients with high adherence scores. Beyond that, it should generally be noted that the prompting of certain issues during the guideline-based interview might have narrowed or limited the answers given. In conclusion, our findings reveal a positive evaluation and a patient and GP perceived benefit of the theory-based intervention, thus fulfilling one requirement for a successful implementation of the intervention. In a next step, the quantitative evaluation of the intervention will be conducted and recommendations for implementation in usual care will be made on the basis of the overall evaluation.

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Competing interests

None declared.

Author contributions

Study conception: MG, EF, SR. Development of interview guideline and coding system: NA. Critical review of the interview guideline and coding system: MB, MG, EF. Data collection and analysis: NA, MB. Data interpretation: NA, MB, MG, EF. Drafting and revision of the manuscript: NA. All authors read, contributed to and approved the final manuscript.

Patient consent for publication

Not required. This manuscript does not contain any patients' individual medical information.

Data sharing

Not applicable.

Ethical approval

The study was approved by the Ethics Committee of the Albert-Ludwigs-University Freiburg (No. 380/18, vote from 22 of November, 2018). Informed consent of each patient is obtained in writing prior to participation.

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Supplemental Material; ANKA et al.

Suppl. Table 1

Interview guideline of patient participants

Welcome and introduction
Introduction of interviewer, aim and procedure of the interview
Interview-questions *(obligatory core questions in bold)*
Evaluation of the telephone intervention (initial question)
Thinking back to the telephone training with the doctor, how did you find that conversation?
How did you feel about the conversation?
What do you remember positively/negatively?
How was the information?
Is there something that would have been helpful for you to know but which did not come up during the phone call? If so, what?
How did you feel about the duration of the phone call?
Experience in implementing the preventative measures
How was the implementation of the preventative measures in your daily life?
What went well? What was easy for you to implement?
Were there any difficulties in implementing some of the precautionary measures? Was anything cumbersome or difficult to implement?
[If yes,] how did that go? What helped you?
Did you discuss these steps with the doctor on the phone beforehand? How was that for you?
What are the next steps concerning the prevention measures?
Dealing with sepsis risk
You have also talked about the increased risk of sepsis with the doctor. How did that go?
Are you now more concerned about developing a sepsis? If yes, why?
Do you feel able to deal with the risk?
Supplementary block: Information material
How do you rate the information material that was sent to you by post?
Conclusion and acknowledgement
Do you want to address something we have not talked about yet?

Supplemental Material; ANKA et al.

Suppl. Table 2

Interview guideline of doctor participants

Welcome and introduction
Introduction of interviewer, aim and procedure of the interview
Interview-questions *(obligatory core questions in bold)*
Evaluation of the telephone intervention (initial question)
When you think back to the conversation with the doctor from the university hospital, how did you feel about it overall?
What did you like / less like? Do you have any specific improvement suggestions?
How (comprehensible) was the information? Which of the information did you find most (or least) helpful?
Is there something that would have been helpful for you to know, but which did not come up during the phone call? If so, what?
What did you think of receiving the information on the phone? Do you think the written information (without the phone call) would have been sufficient?
How did you feel about the duration of the phone call?
Usefulness of the intervention
Did the information influence your further treatment or education of the affected patient?
If so, how? What information specifically?
If not, for what reason?
Written information material
How do you rate the information material that was sent to you by post?
Online information
The information material included a web address for a website on asplenia. Did you use it and, if so, how?[1]
Expert question
In your view, is there (anything else) that we could improve?
Conclusion and acknowledgement
Do you want to address something we have not talked about yet?

[1] During the telephone intervention, doctors were referred to an asplenia-website for further information. As this aspect is not relevant for the present work, no corresponding results are reported.

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BMC Infectious Diseases

STUDY PROTOCOL

Open Access

Prevention of post-splenectomy sepsis in patients with asplenia - a study protocol of a controlled trial

Marianne Bayrhuber[1†], Natascha Anka[1†], Johannes Camp[2], Manuela Glattacker[1], Erik Farin[1] and Siegbert Rieg[2*]

Abstract

Background: Patients with asplenia have a significantly increased lifelong risk of severe invasive infections, particular post-splenectomy sepsis (PSS). Clear preventive measures have been described in the literature, but previous studies found poor implementation of prevention recommendations. Aim of the study is to improve the adherence to guideline-based preventive measures and thereby reduce the incidence of PSS by a novel telephone-delivered intervention that involves both patients and their physicians.

Methods: A prospective controlled, two-armed historical control group design is used to evaluate the new intervention compared to usual care. The intervention for patients includes both educational aspects and, building on the Health Action Process Approach (HAPA), intervention components that promote motivation and planning of preventive measures. For physicians the intervention is primarily information-based. The primary outcome, the adherence to preventative measures, is indicated by a study-specific 'Preventing PSS-score' (PrePSS-score), which is assessed at baseline and at 6-months follow-up. Secondary outcomes include, amongst others, patient self-efficacy and action-planning, asplenia-specific health literacy, general self-management and asplenia-specific self-management. In a process-evaluating part of the study interview-data on patients' and physicians' evaluation of the intervention will be gathered.

Discussion: This trial will provide evidence about the effectiveness of the novel prevention intervention for asplenic patients. If demonstrated beneficial, the intervention manual will be made publicly available to enable implementation in practice. The experience gained within this trial may also be valuable for prevention strategies in patients with other diseases.

Trial registration: German Clinical Trials Register (DRKS): DRKS00015238; Trial registration date 07. December 2018.

Keywords: Asplenia, Post-splenectomy sepsis, Overwhelming post-splenectomy infection, Telephone intervention, Sepsis, Splenectomy, HAPA, Vaccination, Prevention

Background

The spleen is the largest lymphatic organ and plays a crucial role in linking innate and adaptive immunity. As a result, the absence of the spleen is associated with significant morbidity and mortality [1]. Patients with anatomical asplenia (partial or total surgical removal of the spleen) or functional asplenia (loss of function of the spleen) have a significantly increased lifelong risk of severe invasive infections [2, 3]. The mortality of post-splenectomy sepsis (PSS, also called overwhelming post-splenectomy infection [OPSI]), the most dangerous complication, reaches 30–50% [4]. Studies report incidence rates of 7–8 infections requiring hospitalization per 100 patient-years and a post-splenectomy sepsis incidence of 1 per 100 patient-years. Compared to the general population, patients with asplenia have an approximately 6-fold increased risk of sepsis-related hospitalization [5].

The high mortality of these infections has led to guidelines for the prevention of sepsis in asplenic and

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hyposplenic patients. These recommendations include patient education, vaccinations, prophylactic and stand-by antibiotics, medical alert cards, travel advice and early treatment of animal bites [6, 7]. Patients without a functioning spleen and their physicians should be educated about the everyday risk of overwhelming infections and the need of prompt recognition and treatment of infections.

Asplenic patients should receive sequential pneumococcal vaccination (13-valent conjugate followed by 23-valent polysaccharide vaccine), meningococcal vaccination (tetravalent ACWY and serotype B vaccine), *Haemophilus influenza* type b conjugate vaccine and yearly influenza vaccination. A stand-by antibiotic should be prescribed for emergency use ('pill in the pocket'). A smaller subgroup of patients (age < 5 years, patients after a PSS episode) should obtain antibiotic prophylaxis, although there is no international consensus on when to discontinue prophylaxis. Patients should carry a medical alert card that can inform physicians of the patient's asplenia, optimally. Furthermore, travellers to high-risk areas, for example with regard to malaria, should secure optimal preventive measures. The effectiveness of these prevention measures has been shown in several studies [8–10].

Nevertheless, despite from these clear recommendations, previous studies have found poor adherence to preventive measures [2, 11]. In a recent prospective multicenter cohort study from Germany [12], the vaccination status was queried in patients with PSS admitted to an intensive care unit. Only 21% of patients had been vaccinated in the past 5 years according to the recommendations for asplenic patients with a pneumococcal vaccine; only 6% had ever been vaccinated against meningococci and 12% against *H. influenzae*. Accordingly, only 12% of patients had received a seasonal influenza vaccination. In the asplenia registry study at the Medical Centre University of Freiburg, only 6% of patients treated as part of regular care by general practitioners had completed the vaccination schedule according to current recommendations [12]. The registry data also show impressively that the booster immunization rates for each vaccine are again significantly worse than the primary immunization rates. In addition, only a minority (47%) of patients had received prescriptions for stand-by antibiotics.

Reasons for the lack of adherence to recommended prevention measures could be, on the one hand, that the prevention measures are unknown to patients and physicians [8]. On the other hand, patients might not be aware of the increased risk of infections, which could explain the low adherence to preventive measures. Several studies suggest the 'Health Action Process Approach' (HAPA) as a theoretical framework for the understanding of health behaviour in general [13–15] and for vaccination behaviour in particular [16–18]. The HAPA postulates a two-phase approach to action: Firstly, a pre-intentional motivational phase, which is characterized by risk perception, expectation of action results and expectation of self-efficacy and leads to an intention. And secondly, a post-intentional volition phase, which comprises factors as planning, action control, social support, recovery self-efficacy and leads to the actual health behaviour. Situational barriers and resources also play a role here as they influence the intention, planning and health behaviour. Social support, for example, represents a resource and the lack of it could be a barrier to adopt and maintain health behaviour [19]. Interventions to improve health behaviour beyond the passive provision of information material have not yet been described for asplenic patients.

Aim of the study is to improve the adherence to guideline-based preventive measures and thereby reduce the incidence of PSS by a novel telephone-based intervention that involves both patients and their general practitioners. By educating patients, the intervention contributes to the participation and empowerment of patients, who take responsibility for their own health in general and the implementation of prevention measures in particular. The new intervention is supposed to improve patients' health by reducing morbidity as well as mortality and increase the quality-of-life of patients with asplenia. In addition, it can be expected that the costs of health insurance companies will decrease, since the treatment and follow-up costs of post-splenectomy infections are relatively high compared to the planned intervention and implementation of preventive measures. Evidence for this assumption can be found in cost-effectiveness analyses of PSS prevention in asplenia registries [12, 20]. Furthermore, the development of such an intervention can serve as a model for other studies.

Our assumption is that a targeted intervention strategy increases the adherence to recommended prevention measures.

Methods/ design

Aims and hypotheses

The purpose of this study is to develop, manualize and evaluate a novel intervention that educates both patients and their physicians on appropriate preventive measures that should be undertaken to prevent infections after splenectomy. Besides information provision, the intervention is intended to motivate patients to implement the preventive measures and to convey action-related skills such as planning and managing barriers. It will be evaluated whether this targeted intervention (intervention group) is superior to usual care (historical control group) in terms of primary and secondary study outcomes. More precisely, we have put forward the

following hypotheses as to the outcome of the intervention: (a) Adherence to infection-risk reducing preventive measures will significantly be increased (primary outcome). As a result, (b) the incidence of severe infections associated with asplenia (particular PSS) and (c) related health-care costs covered by health insurances will be reduced (distal secondary outcomes). (d) Risk perception, intention to implementation, perceived self-efficacy, action and coping-planning, positive and negative outcome expectations and received social support (HAPA-related variables) expected to account for the effect of the intervention will significantly be enhanced (proximal secondary outcomes). Furthermore, (e) disease knowledge, patients' general and asplenia-specific self-management, asplenia-specific health literacy, patient involvement as well as health-related quality of life will significantly be enhanced (distal secondary outcomes).

Beside this quantitative outcome-evaluation, intervention patients' and intervention patients' physicians' acceptance and evaluation of the intervention will be inquired in telephone interviews in a process-evaluating part of the study.

Study design and setting

This intervention study is designed as a prospective controlled, two-armed historical control group trial with baseline, post- and follow-up measurement and process evaluation (Fig. 1). The combination of outcome and process evaluation meets the recommendations for evaluating complex interventions [21]. As delaying the delivery of information on preventive measures puts patients on a non-justifiable risk [8] we decided against a randomized design and opted for a design with a historical control group for ethical reasons. In addition, the historical control group optimally illustrates current practice ('usual care').

The study is conducted by the Medical Center - University of Freiburg, Germany (Division of Infectious Diseases, Department of Medicine II and Section of Health Care Research and Rehabilitation Research, SEVERA) and the AOK Baden-Wuerttemberg, Germany.

Intervention

The intervention comprises a telephone-based individual intervention session for patients with asplenia and a separate intervention for their physician, conducted by study physicians of the Medical Center - University of Freiburg with expertise in clinical infectious diseases. The content of the intervention was developed based on comprehensive literature review, existing guidelines for infection prevention and the study physicians' expert knowledge. Both, the intervention sessions for patients and for their physicians are manual-guided to ensure a consistent practice across all study physicians; however, the interview protocol is semi-structured to allow an individualized proceeding. When developing the manual, particular attention was paid to its practical feasibility to enable a future implication beyond this study.

Prior to the implementation of the intervention, all participants are sent patient or physician tailored educational materials with brief information on the prophylaxis options along with a comprehensibly prepared vaccination plan and a medical alert card for patients with asplenia (see Additional file 1). It was developed by the Medical Center – University of Freiburg, the German Society of Infectious Diseases and the German Sepsis Society.

Patient-directed intervention (intervention group)

The 20-min intervention session for patients in the intervention group is divided into an information-giving section and, following the HAPA theory, intervention components that promote motivation for initiation (risk perception, positive outcome expectancies and task self-efficacy) and planning (action and coping planning, maintenance self-efficacy) of recommended infection prevention measures. Applied behavioral change techniques according to Abraham and Michie [22] comprise: providing information about behavior-health link and on the benefits of preventive measures, providing instruction, prompting intention formation, specific goal setting and barrier identification, assisting with relapse prevention by teaching to use prompts or cues or plan social support and use of follow-up prompts.

In the first section patients are provided with evidence-based information on the immunological function of the spleen, on potential infections after the spleen has been removed (targeting risk perception) and are educated on the most important preventive measures (targeting positive outcome expectancies). These comprise receiving asplenia-specific vaccinations (pneumococcal, meningococcal and *Haemophilus influenza* type b) and annual influenza vaccinations. Moreover, patients are advised to have an emergency supply of 'pill in the pocket'-antibiotics to be taken in the event of sudden illness. The medical alert card for asplenic patients that informs health professionals about the splenectomy is introduced to them.

In the motivational-section patients are informed about the efficacy of the recommended preventive measures by means of a brief example on morbidity rates found to be higher among asplenic patients who are presumably unaware of their increased infection risk than among patients who received preventive education (targeting risk perception and positive outcome expectancies). Participants are sensitized to signs and symptoms that may indicate infection and are educated about the need of seeking rapid medical attention or taking

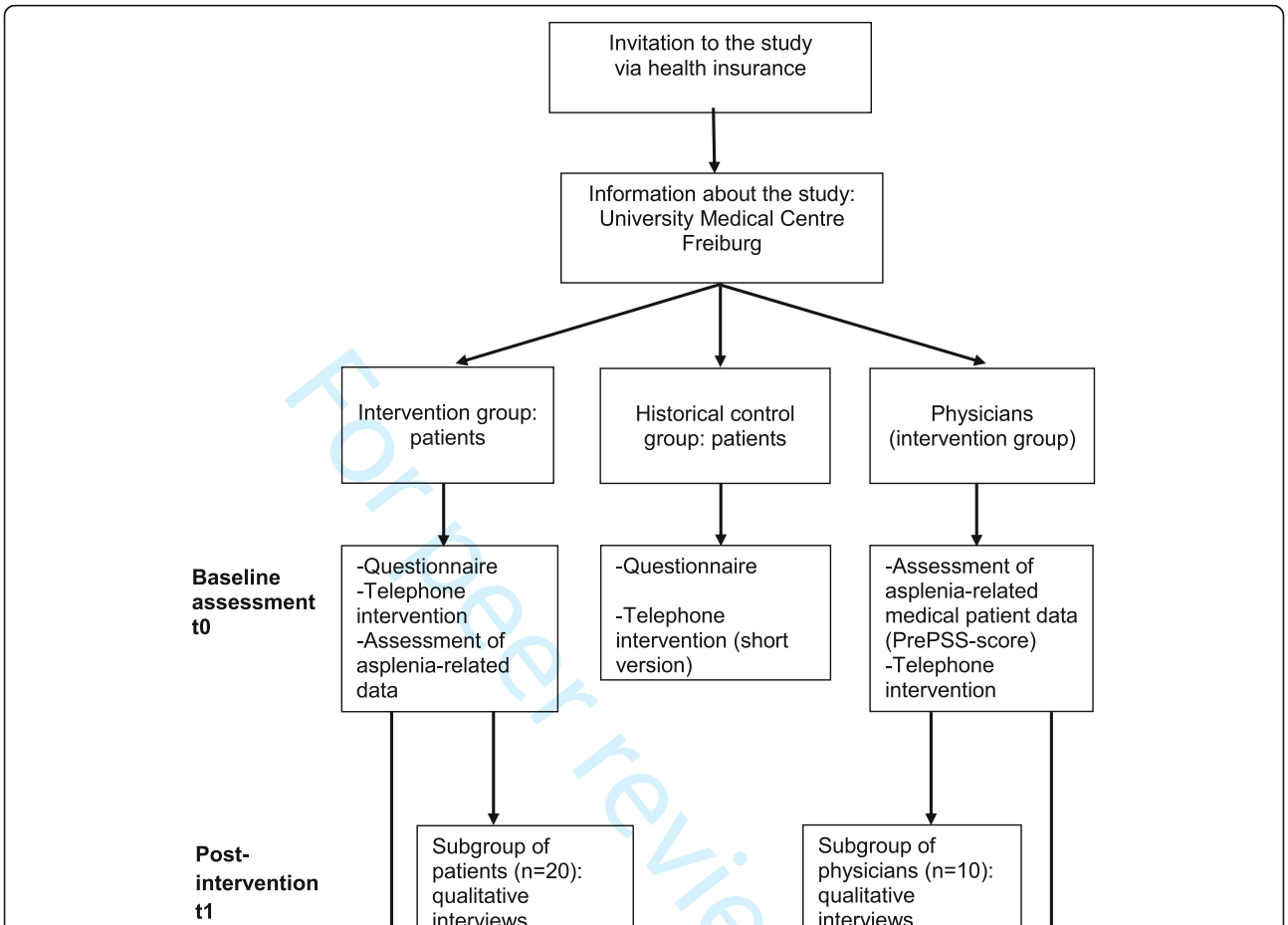

Fig. 1 Flow chart of the study-design

emergency stand-by antibiotics if residing far from medical care and symptoms of infection occur (targeting task self-efficacy). In doing so, the information is framed in a way as to increase the awareness of the patient's personal relevance rather than arousing fear of disease and it is focused on the feasibility of the recommended prevention behavior [23]. After explanation, patients are encouraged to determine which recommendations they want to follow by ticking corresponding boxes on their worksheets to prompt goal-setting.

In the planning-section patients are told that the aim is to facilitate implementation of the previously set prevention goals by precise planning. They are asked to develop action plans defining when, where and how they would take the intended infection preventive measures, including necessary preparatory behaviors, e.g. making appointments, fill in the medical alert card by physician (targeting action planning). Beyond that, participants are prompted to anticipate potential personal barriers to implementation of their personal plans. Amongst others, they are encouraged to think of situations in which the medical alert card could presumably be forgotten or circumstances that may led them failing to complete a vaccination course. At the same time, patients are assisted to find ways to attain their goals despite the identified impediments, for instance by seeking support

from their networks (targeting maintenance self-efficacy and coping planning). To promote transfer into participants' everyday lives they are encouraged to record their individual action and coping plans on designated worksheets accompanying the session.

At the follow-up telephone call, all planned preventive measures are assessed in order to calculate the PrePSS-score and, when indicated, potential barriers to implement plans are discussed. If further assistance for implementation is assumed, participants are re-motivated and assisted to manage difficulties. Follow-up consultation is optional and individually tailored to the patients' needs and not manual-based.

Short version of the patient-directed intervention (historical control group)

Patients in the historical control group receive a shortened version of the patient-directed intervention. The short version includes the information-giving section on the functioning of the spleen and on health implications of asplenia (targeting risk perception, outcome expectancy and task self-efficacy) as well as the motivational-section on the efficacy of the recommended precautions and on strategies for risk situations (targeting positive outcome expectancy and task self-efficacy) since it is important for ethical reasons that the control group is provided with the same precautionary information as the intervention group. However, the planning-section is absent from the control group's intervention as specific action plans and potential barriers are not discussed due to a lack of time resources. The intervention in the control group is implemented only for ethical reasons and is not an intervention variant to be evaluated. Data collection relevant for the study has already been completed in this group at the time of intervention implementation, thus a confounding influence on the outcome variables can be ruled out.

Physician-directed intervention

The physician-directed telephone intervention comprises evidence-based information on the consequences of asplenia and the increased infection risk associated with high mortality rates. Physicians are educated about preventive measures consistent with current post-splenectomy guidelines including currently recommended vaccination and revaccination on the basis of given immunization schedules, indication of stand-by antibiotics and antibiotic prophylaxis. Furthermore, the intervention session includes an introduction in the purpose and use of the medical alert card and the necessity of patient education, particularly as to the patient-initiated antibiotic use in case of febrile illness. Physicians are advised to document any antibiotics in use and record a vaccine plan (vaccination status, need and interval for revaccination) specific to their patient using provided fields on the medical alert card.

The objective of the intervention is to heighten physicians' awareness and knowledge of available preventive measures to improve guideline-based post-splenectomy care. Thereby the information-provision component is the integral part of the physician's intervention. However, in line with the patients' intervention, the physicians' intervention also targets risk perception, positive outcome expectancy and, subsequently, motivation to follow guideline recommendations.

The intervention sessions take approximately 10 min. All participating physicians receive the intervention irrespective of the group allocation of their patients.

Participants and recruitment

Participants are patients with anatomic asplenia and their physicians (general practitioners or specialists). Eligible are German-speaking patients aged 18 years or older, who are insured by the cooperating health insurance AOK Baden-Wuerttemberg, which is Germany's 5th largest health insurance and insures more than 4 million people.

Patient participants are preselected to either the intervention or control group based on the time interval since they underwent splenectomy. Patients who are recently splenectomized (at most 4 months) are allocated to the intervention group. Potential intervention patients are recruited about 6–8 weeks after splenectomy successively by biweekly request from February 2019 for a maximum period of 18 months. The historical control group consists of patients who are splenectomized since more than 6 months (at most 18 months). Thus, pre-interventional baseline-data on primary and secondary outcomes in the historical control group account for routine care. Potential control group patients were recruited at the start date of study implementation (January 2019) and, to attain the planned sample size, another cohort of patients was contacted half a year later (June 2019).

Potential patient participants are identified via a database search (search criteria: OPS-code 5–413 splenectomy, with all sub-codes 5–413.0 [partial splenectomy] and 5–413.1 [total splenectomy]) for all splenectomized patients within the predefined group-specific time periods since splenectomy by the AOK-Baden-Wuerttemberg. Patients who meet criteria receive recruitment letters from the health insurance. Those who are interested in study participation receive detailed information on the procedure, the aims and the legal conditions of the study from the University Medical Centre Freiburg. Participants are asked to provide written informed consent and contact information if they agree to take part.

To identify the corresponding physician, participating patients are asked to provide contact information on their general practitioner or other physician who mainly cares for their asplenia and sign an agreement releasing the physician form medical confidentially obligation. Physicians whose patients consent to having their physicians included in the study are recruited by letters with information concerning the study. No exclusion criteria for physicians are applied. Both patient and physicians will receive a 30€ voucher for participation after study completion.

Sample size considerations

A priori calculation of the sample size of patient participants to compare the intervention group to the historical control group in the primary outcome was performed with the software '*Power and Precision*'. Based on an assumed medium to large effect size of 0.40, a statistical power of 80% and a significance level of 5% (two-sided) the minimum required patient sample of $N = 100$ per group was calculated. Further sample size considerations take into account the actual number of splenectomized patients insured by the AOK. An explorative request showed that 360–400 patients undergo splenectomy a year, resulting in approximately 500 patients assumed to be available for recruitment in the planned inclusion period of 18 months. Based on studies with similar patients [24], we further estimated a proportion of 50% non-respondents for the intervention group and attrition rates of 40% of respondents, so we aim to recruit 500 potential intervention group patients for an expected analysis sample of $N = 178$ participants. As this exceeds the statistically required number of cases despite conservative estimations, sufficient cases will be available even after considering potential deceases in the course of the study.

Given that the inclusion period (18 months) is the same for the control group (although retrospectively), sample size considerations for this group are largely the same, with the exception of an assumed proportion of 60% non-respondents and a dropout rate of 50%, resulting in expected $N = 110$ control group cases for analysis. Correspondingly, the number of physician participants included in analysis will be $N = 178$ intervention patients' physicians and $N = 110$ control patients' physicians maximum, considering that some patients may have the same physician.

Outcome measures

Primary outcome

The primary outcome, the adherence to preventative measures, is indicated by a study-specific 'Preventing PSS-score' (PrePSS-score), which includes the following parameters: (a) receipt of guideline-conform sequential pneumococcal vaccination and (b) guideline-conform meningococcal vaccinations, (c) prescription and availability of stand-by antibiotics for emergency treatment and (d) handing out of and carrying a medical alert card for asplenic patients. The selection of the included parameters was made by Infectious Diseases specialists of the University Medical Center Freiburg based on current guidelines and recommendations on PSS prevention [25, 26].

To weight these preselected parameters, an expert survey was conducted prior to the study asking a total of 16 international experts in the care of asplenic patients to rate the items according to their importance in infection prevention, of which nine experts provided feedback. Based on the calculated median of the given expert-ratings the scoring system was defined (see Table 1 for an overview, for exact score formation and operationalization see Additional files 2 and 3).

The score for each patient is estimated by the study physicians according to both the patient's and the physician's information gathered through telephone-interviewing. To validate the self-report data on the primary outcome, health insurance patient routine data aggregated by groups (vaccinations relevant to asplenia and prescribed antibiotics) will be included.

Secondary outcomes

In this article secondary patient outcomes are classified on a proximal-distal continuum of outcome measures [27]. HAPA-related variables (i.e. patient's risk perception, self-efficacy and action-planning) are considered as *proximal secondary outcomes* which are assumed to be more likely and directly affected by the intervention than distal outcomes and observable shortly after the intervention. More global, *distal secondary outcomes,* are assumed to be also influenced by proximal outcomes as well as external, non-treatment factors. These include disease knowledge (disease knowledge is also expected to be a confounder), patient general and asplenia-specific self-management as well as asplenia-specific

Table 1 Parameters and scoring system of the PrePSS-score

Parameter	Score
(1) Guideline-conform sequential pneumococcal vaccination	0–3
(2) Guideline-conform meningococcal vaccination	0–3
(3) Stand by-antibiotic prescribed and available ('pill in the pocket')	0–2
(4) Handing-over and carrying a medical alert card	0–2
Total PrePSS-score [Range]	0–10

health literacy, self-reported patient involvement and health-related quality of life.

Secondary outcomes for physician participants are their subjective improvement in knowledge and their satisfaction with the intervention.

Questionnaires

Patient-related secondary outcome measures, potentially confounding variables and the patients' evaluation of the telephone-intervention are assessed via self-administered paper-pencil questionnaires incorporating already validated instruments as well as asplenia-specific scales developed for the purpose of this study, which are described below.

(1) **HAPA-related outcomes.** To gather key HAPA variables addressed in the intervention, perceived disease risk relevant to asplenia, patients' behavioral intention to implementation, perceived self-efficacy for implementation, action and coping planning, positive and negative outcome expectations and received social support are assessed. Items were developed on the basis of the general assessment rules for HAPA constructs provided by Schwarzer et al. [19] and slightly adapted to infection prevention behavior in asplenia. Responses are rated on a six-point scale ranging from *fully correct* (1) to *not correct at all* (6) (except the scale *risk perception*).
Six items measuring *behavioral intention* to obtain prevention refer, for instance, to "undertake preventive measures recommended after splenectomy" and "obtain vaccinations". *Perceived self-efficacy* is assessed by ten items asking participants to rate their level of confidence in their ability to implement and cope with preventive measures, such as "I can correctly interpret symptoms of a severe infection" or "I will renew my emergency antibiotics after the expiration date". *Prevention behavior planning* is assessed with six items, four items measuring action planning as the items address the where and how of the precautions (e.g. "what kind of vaccinations I will get done") and two items measuring coping planning asking for situations that could interfere with their plans (e.g. "what I can do if I forget my emergency antibiotics"). *Positive and negative outcome expectancies* after implementing the preventive measures are assessed with three items asking for pros, e.g. "I'm better protected from the flu" and three items asking for cons, e.g. "I could suffer from side effects of vaccinations". *Received social support* regarding prevention implementation is measured with the stem "People around me (e.g. family, friends)…" followed by five items, for example "have encouraged me to take preventive measures recommended after splenectomy". For *risk perception*, the item stem "If I compare myself with other people (of my age and sex), then my risk, sometime in future…" is followed by the items "to fall ill with blood poisoning", "to fall ill with meningitis" and "to get pneumonia", which are rated by participants on a scale from *significantly increased* (1) to *considerably lower* (5).

(2) **Self-management.** General self-management is assessed with the two subscales *Self-Monitoring and Insight* and *Skill and Technique Acquisition* from the German version of the Health Education Impact Questionnaire (heiQ) [28, 29], a widespread tool developed to assess proximal outcomes of patient self-management programs, covering eight independent dimensions. The scale *Self-Monitoring and Insight* (six items) captures individuals' ability to monitor their condition that leads to insight and appropriate actions to self-manage as well as individuals' acknowledgment of realistic disease-related limitations. The scale *Skill and Technique Acquisition* (four items) covers the subjective appraisal of knowledge-based skills and techniques that help manage disease-related symptoms and health problems. Items are scored on a 4-point response scale (1 = *strongly disagree* to 4 = *strongly agree*) and averaged for the two scales, with higher values indicating a higher subjective judgement of self-monitoring and skills respectively.

(3) **Asplenia-specific self-management and asplenia-specific health literacy.** To capture disease-specific self-management components, five items related to asplenia were developed on the basis of the heiQ-scales *Self-Monitoring and Insight* (three items) as well as *Skill and Technique Acquisition* (two items), described above. One item each derived from the heiQ-scales *Health-Service Navigation* and *Social Integration and Support* were used to develop two further items as these aspects are additionally relevant for asplenia-specific self-management.
A total of six items capturing asplenia-specific health literacy were derived from the Health Literacy Questionnaire (HLQ) [30]. The HLQ covers nine health literacy domains that reflect an individual's competencies and experiences when attempting to understand, access and use health-information or when trying to engage with health-care practitioners or services, of which five were used as basis for the development of the disease-specific health-literacy items. The response format for all self-developed items is a 6-point scale

ranging from *fully correct* (1) to *not correct at all* (6).

(4) **Patient involvement.** Patient involvement is measured with the German version of the Perceived Involvement in Care Scales (PICS) [31, 32] a 14-item generic instrument that is designed to assess patients' perceptions of participation in treatment decision making as well as physicians' efforts to facilitate patient involvement. It covers three categories of patient-physician communication: *Doctor Facilitation of Patient Involvement, Level of Information Exchange* and *Patient Participation in Decision Making*. The response scale is a 4-point Likert scale ranging from 1 (*strongly disagree*) to 4 (*strongly agree*), where higher scores indicate higher perceived patient activity and endorsement.

(5) **Health-related quality of life.** The 12-item Short-Form-Health-Survey (SF-12, short version of SF-36) is administered to assess self-reported health-related quality of life referring to the past 4 weeks [33]. The SF-12 is a generic instrument that yields a subjective mental and physical health status summary score derived from four health components respectively: Physical health comprises *general health, physical functioning, role limitations due to physical health problems* and *bodily pain*; subjective mental health comprises *vitality (energy/ fatigue), social functioning, role limitations due to emotional problems* and *mental health*. High scale values indicate better health.

(6) **Subjective and objective disease knowledge**. Subjective disease knowledge held by patients is assessed using two items asking them to rate their level of knowledge about the consequences of splenectomy and potential preventive measures on a 5-point scale (1 = *very great knowledge* to 5 = *non-existent knowledge*). Four additional questions are administered to ascertain the objective degree of knowledge about asplenism. The items refer to the functions of the spleen, consequences of splenectomy, recommended precautions and patients theoretically behavior in case of sudden septic symptoms (of which the latter is derived from Gundling et al. [33]).

(7) **Compliance and influenza prevention behaviors.** Patients' compliance with general health-preserving measures is estimated using four items of the German version of the Questionnaire of Multiple Health Behavior (MHB-39) [34] that load highest onto the domain *Compliance* (i.e. having regular check-ups and prophylactic vaccinations made, complying with physicians and consulting a doctor when indicated). The MHB-39 assesses habitual health-related behaviors on a 5-point Likert scale (1 = *never* and 5 = *always*). In our questionnaire, the MHB-39 compliance-items are supplemented by three questions asking for patients influenza prevention behaviors (i.e., washing hands after return to home and before touching food, avoid touching eyes or mouth in public, avoid hand shaking during flu season) taken from Zhang et al. [16] and translated into German.

(8) **Depression and anxiety.** Indicators of depression and anxiety in patient participants are measured using the German version of the Patient Health Questionnaire for Depression and Anxiety (PHQ-4) [35], a validated four-item ultra-brief screening instrument that consists of a 2-item *depression scale* (Patient-Health-Questionnaire, PHQ-2) [35, 36] asking for DSM-IV diagnostic core criteria symptoms (i.e. loss of interest, depressed mood) and a 2-item *anxiety-scale* (Generalized Anxiety Disorder Scale, GAD-2) [36] representing core symptoms of a generalized anxiety disorder (feeling nervous and anxious, difficulty to stop or control worrying). The stem question for all items is: "Over the last two weeks, how often have you been bothered by any of the following problems?". Answers a given on a 4-point Likert-type scale ranging from *not at all* (0) to *nearly every day* (3). Scale scores ≥3 indicate the presence of a depression or an anxiety disorder, respectively.

(9) **Evaluation of the telephone-intervention.** Patients are asked to judge patient-centered criteria of the telephone-intervention using six items relating to the content (i.e. topic selection, comprehensibility, and usefulness), materials and interaction (atmosphere, opportunity to make own comments or pose questions). Items are rated on a school grading scale ranging from (1) *very good* to (6) *very poor*. Two further open questions inquire positive feedback and suggestions for improvement. Items were taken from Meng et al. [37] and slightly adapted to our intervention.

Procedure

The chosen outcomes for patients are measured prior to the intervention (baseline measurement, t0), directly after the intervention (t1) and after a 6-month follow-up period (t2).

At t0, patients in the intervention group are sent paper-pencil pseudonymized questionnaires on baseline proximal and distal secondary outcomes and socio-demographic information. Upon receipt of the filled questionnaires, telephone appointments are arranged with patients for a study physician interview. During telephone calls, a vaccination history, use and availability of stand-by antibiotics and the medical alert card are

taken to gather baseline data on the primary outcome, the PrePSS-score, along with some other medical information relating to the patients' asplenia (e.g. indication for splenectomy, splenectomy date and previous episodes of infection or PSS requiring hospitalization).

After t0-data collection, the patient-directed telephone-intervention is implemented. The intervention of the corresponding physician is conducted at about the same time; however, the order is determined by the arrangement of the telephone appointments and not standardized. Secondary physician outcomes are gathered after the physician-directed intervention. Historical control group patients and their physicians go through the same procedure and patients receive t0-questionnaires identical to intervention group patients, but only intervention participants continue measurement after the telephone intervention.

Following each patient telephone call, intervention patients complete post-intervention questionnaires on the proximal secondary outcomes similar to baseline items and evaluate the telephone-intervention (t1).

To test for six-month sustainability of the effects of the intervention they receive follow-up questionnaires on distal secondary outcomes identical to baseline measurement (t2). After return of the follow-up questionnaires, intervention patients are contacted by study physicians via telephone again to inquire the same set of data on the primary outcome and (changes in) medical data, such as the incidence of infections and PSS, gathered at t0.

To ensure a valid data basis, patients' self-report data on the primary outcome variable and on the medical information are confirmed with the corresponding physician both at t0 and (in the intervention group) at t2. In case physicians are interviewed prior to their patients, patients are made aware of any discrepancies between their information and information their physicians provided when required.

Qualitative interviews for process evaluation

A total of 20 patients of the intervention group and 10 intervention patients' physicians (first patients or physicians who agree to participate) are surveyed 5.5 months after telephone-intervention (shortly before t2-measurement) in semi-structured 20- to 30-min telephone-interviews by psychologists of the project team. Patients are interviewed on their acceptance and perception of the telephone-intervention and accompanying materials as well as on the feasibility (e.g. experience in implementation, helpful factors and barriers) of intervention contents. Physicians are asked for their subjective evaluation of the intervention (e.g. usefulness, improvement suggestions). Interviews will be audio-recorded with the permission from participants.

Data analysis

Demographic characteristics of the study population and effect sizes in the intervention group will be reported descriptively. The main analysis tests the hypothesis that the PrePSS-score at follow-up is higher (better adherence to infection-risk reducing preventive measures) in the intervention group than in the control group. Due to the non-randomized design a propensity score adjustment is performed to reduce potential bias that may be caused by differences on covariates in the two groups [38]. We will apply general linear models with propensity score as a covariate. The same method will be used for the analysis of secondary outcomes. Assuming missing data in the questionnaires, multiple imputation will be considered for corresponding analyses. Additional analyses will be conducted with structural equation modeling technique to test a priori specified mediation models of intervention effects.

A cost-effectiveness analysis of the intervention will be conducted by analyzing the change-from-baseline scores of the primary and the secondary outcomes in relation to the costs of the intervention. To reveal the economic efficiency of the intervention, routine data will be used to determine standard treatment and follow-up costs associated with infections requiring hospitalization and with PSS in asplenic patients to contrast them to the intervention costs.

In the qualitative analyses, the audio files of the interviews will be transcribed by an external service provider and the transcripts will be analyzed using a qualitative content analysis.

Discussion

Poor implementation of the prevention recommendations for patients without a functioning spleen has been demonstrated in several studies. Better adherence to preventive measures is urgently needed [2, 11]. However, conclusive and effective new strategies to improve care beyond the passive provision of information have not yet been described for asplenic patients.

Strengths of the current study are the development and evaluation of a theory-based dual intervention, i.e. focusing on patients and their physicians. By educating and training patients, the intervention contributes to the empowerment of the patients. Quantitative data will allow us to evaluate the effect of the intervention on prevention measures such as vaccinations, prophylactic and stand-by antibiotic use and patient-related outcomes. Qualitative interviews will enable us to understand e.g. barriers in preventive behaviour. Furthermore, the new intervention can be improved on the basis of feedback from asplenic patients and their physicians. Following this evaluative process, the intervention-manual will be

made publicly available to enable future implementation in practice.

The study has some limitations, which are mainly based on our sampling strategy. First, our sample contains a self-selected group of patients from the co-operating health insurance (AOK Baden-Wuerttemberg). Secondly, it is not a randomized controlled trial, however, due to above outlined ethical reasons randomization is not justifiable. In order to reduce a potential bias that may be caused by differences in covariates in the intervention vs. historical control group, propensity score matching will be applied. Third, the primary outcome, the PrePSS-score was developed via expert-ratings, however, weighting of the four included items may still need further refinement and research.

All in all, we believe that the experience gained with this type of intervention will also be very valuable for prevention strategies in patients with other diseases. The intervention could be considered - after demonstrated effectiveness - in the context of other poorly implemented primary prevention measures or standard vaccinations, e.g. influenza and pneumococcal vaccination in patients over the age of 60 years.

Supplementary information

Supplementary information accompanies this paper at https://doi.org/10.1186/s12879-019-4752-2.

Additional file 1. Medical Alert Card Asplenia.

Additional file 2: Table S2. Results of the expert survey.

Additional file 3: Table S3. Operationalization of the PrePSS-score parameters after weighting of the parameters.

Abbreviations

GAD-2: Generalized Anxiety Disorder Scale; HAPA: Health Action Process Approach; heiQ: Health Education Impact Questionnaire; HLQ: Health Literacy Questionnaire; MHB-39: Questionnaire of Multiple Health Behavior; OPSI: Overwhelming post-splenectomy infection; PHQ-2: Patient-Health-Questionnaire; PHQ-4: Patient Health Questionnaire for Depression and Anxiety; PICS: Perceived Involvement in Care Scales; PrePSS-score: Preventing PSS-score; PSS: Post-splenectomy sepsis; SF-12: 12-item Short-Form-Health-Survey

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Authors' contributions

Drafting and revision of the manuscript: NA, MB. Initiation, conception, design and coordination of the research project: SR, MG, EF. Development of the intervention and evaluation materials: MB, NA, MG, EF. Implementation of the intervention: SR, JC. All authors read and approved the final version of the manuscript.

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Availability of data and materials

Not applicable.

Ethics approval and consent to participate

The study (including all information materials and forms for the written informed consent for patients and physicians) was approved by the Ethics Committee of the Albert-Ludwigs-University Freiburg (No. 380/18, vote from 22 of November, 2018). Informed consent of each patient is obtained in writing prior to participation.

Consent for publication

Not applicable. This manuscript does not contain any individual person's data.

Competing interests

The authors declare that they have no competing interests.

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Publisher's Note

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	9
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	1
Occupation	3	What was their occupation at the time of the study?	9
Gender	4	Was the researcher male or female?	9
Experience and training	5	What experience or training did the researcher have?	9
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	9
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	9
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	9
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	9
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	6-8
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	6
Sample size	12	How many participants were in the study?	7-8
Non-participation	13	How many people refused to participate or dropped out? Reasons?	7-8
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	9
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	9
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	6
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	8
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	10
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	9
Field notes	20	Were field notes made during and/or after the inter view or focus group?	9
Duration	21	What was the duration of the inter views or focus group?	10-11
Data saturation	22	Was data saturation discussed?	not applicalble
Transcripts returned	23	Were transcripts returned to participants for comment and/or	9

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	10
Description of the coding tree	25	Did authors provide a description of the coding tree?	11-12
Derivation of themes	26	Were themes identified in advance or derived from the data?	9-10
Software	27	What software, if applicable, was used to manage the data?	10
Participant checking	28	Did participants provide feedback on the findings?	9
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	12-20
Data and findings consistent	30	Was there consistency between the data presented and the findings?	12-20
Clarity of major themes	31	Were major themes clearly presented in the findings?	12-20
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	12-20

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

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Asplenic patients' and doctors' experiences in implementing preventative measures following a novel educational intervention: a qualitative analysis

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Asplenic patients' and doctors' experiences in implementing preventative measures following a novel educational intervention: a qualitative analysis

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ABSTRACT

Objective: To explore asplenic patients' and GPs' (1) perceptions of a novel, *Health Action Process Approach* (HAPA)-based, educational intervention which targets to increase adherence to post-splenectomy sepsis (PSS) prevention measures and (2) their experience in implementing prevention measures following this intervention.

Design: A process evaluation conducted on average 3.5 (for patients) and 3.8 (for GPs) months after the intervention between January 2020 and April 2021 individually by means of semi-structured guideline-based telephone-interviews. Data was analysed using qualitative content analysis.

Participants: Volunteer sub-sample of N = 25 asplenic patients and N = 8 GPs who received the intervention. Inclusion criteria were met by prior participation in the intervention (German-speaking, of full age and insured by the cooperating health insurance). Patient selection was done by purposeful selection aiming at maximum variability in terms of adherence to preventative measures prior to intervention participation. Participating GPs are a non-purposeful selected convenience sample. For reasons of data protection, no personal data was collected.

Results: The intervention was positively evaluated and its personal relevancy for patients and for the GPs' professional work became apparent. The intervention promoted risk awareness, intention to action, action planning and subsequently, improved adherence to preventative measures. Helpful factors for implementation among the patients were social support by relatives and GPs. Barriers to adherence identified in both groups can be divided into patient-attributed (e.g. comorbidities), doctor-related (e.g. lack of knowledge or support) as well as contextual factors (e.g. vaccine supply constraints).

Conclusions: Our findings indicate a patient and GP perceived benefit of the intervention, but still identify prevailing barriers to implementation. In a further step, a quantitative evaluation of the intervention will be conducted and recommendations for integrating the intervention in usual care will be made.

Trial registration: German Clinical Trials Register (DRKS): DRKS00015238; Trial registration date is 7th December 2018.

Keywords: Asplenia, Post-splenectomy sepsis (PSS), Sepsis, Splenectomy, General practitioners (GPs), Prevention, Intervention, Health Action Process Approach (HAPA), Interviews, Qualitative Content Analysis, Barriers

Article Summary

Strengths and limitations of this study

- This is the first study in the field of asplenia that explores in depth patients' and GPs' experiences in implementation of PSS preventative measures following an intervention intended to increase adherence.
- Purposeful selection of patients which aimed at maximum variation regarding their pre-interventional adherence enabled to explore a sample with diverse initial experiences in preventative behaviour.
- A minor limitation as regards to the intended maximum variation selection is that very high levels of adherence did not occur in the sample.
- Since participation in the interview, which serves as the data basis in this study, was a voluntary additional effort, a positive bias might have been induced.

INTRODUCTION

Patients with an absent or dysfunctional spleen are susceptible to infectious diseases throughout their lives and are at an increased risk of developing an post-splenectomy sepsis (PSS; also called overwhelming post-splenectomy infection, abbr. OPSI)[1], with a mortality rate up to 50%[2]. According to international clinical guidelines, OPSI is largely preventable through prophylactic measures in this patient population[3]. These measures include amongst others anti-pneumococcal and anti-meningococcal vaccination, permanent availability of a medical alert card and an antibiotic supply for emergency fever treatment ('pill in the pocket') as well as patient education.

However, there is widespread evidence, that guideline awareness and adherence are low[1]. Even if the doctor's knowledge and attitude towards guidelines was found to be appropriate, patient education by health providers as well as inter-sectorial communication were described as insufficient[4]. Thus, many asplenic patients have poor knowledge about the risk associated with their condition and existing prevention recommendations[i.a. 5-7]. Beyond these knowledge (transfer) gaps mainly reported in literature, barriers such as safety concerns, scepticism and the doubted need for vaccination are further reasons that were found for asplenic patients' non-adherence[8]. As better patient knowledge can be considered a key factor in improving adherence[9], and primary care providers are critical in patient education and prevention implementation[8, 10], we developed a novel educational intervention for both asplenic patients and for their general practitioners (GPs) (for a detailed description of the intervention see[11]).

The intervention is a manual-based individualised telephone counselling on evidence-based information of the spleen, asplenia-related infection risks and infection prevention recommendations, conducted by an infectious diseases specialist. The *Health Action Process Approach* (HAPA), a framework that provides predictors for initiation and maintenance of preventative behaviour[12], including vaccination behaviour[i.a. 13], served as theoretical basis. Distinguished into two phases in the HAPA, these predictors include risk perception, outcome expectancies and perceived task self-efficacy which influence the formation of an

intention (*motivational phase*) as well as action and barrier coping planning and maintenance self-efficacy that lead to the actual behaviour (*volitional phase*). Accordingly, our intervention includes specific components which promote motivation for initiation as well as action-related strategies such as planning and managing barriers, the latter being realised through a customisable action plan for patients. For doctors, the intervention is primarily information-orientated by conveying current guideline recommendations for asplenic patients in general and the attending patient specifically. Accompanying the telephone intervention, participants receive written information tailored both to patient and doctor, along with a plain vaccination schedule and a medical alert card.

The intervention is currently being evaluated in terms of its effectiveness in a two-armed historical control-group design. Moreover, as recommended for complex interventions[14], the intervention was evaluated in a qualitative process evaluation. The findings of the process evaluation will be reported in the present article, the quantitative findings will be reported elsewhere. The aim of the process evaluation is to investigate how patients and doctors evaluate the intervention and how they perceive its usefulness for implementation, with particular attention to health behaviour changing factors according to HAPA. And notably, the objective is to gain a deeper understanding of the participants' experience in implementing the preventative measures post-intervention, including factors that influence adherence, that are subjectively perceived barriers as well as helpful factors.

METHODS

Study design

This is a qualitative interview-study conducted with asplenic patients and attending GPs. To ensure the reliability and rigor of our results the methods and the findings are presented in accordance with the consolidated criteria for reporting qualitative research (COREQ) checklist[15] (See supplementary file 1). The research design was based on two steps: 1) A semi-structured interview guideline according to Helfferich (2011) [16] was developed in a multi-step process under comprehensive review of the whole team (See supplementary file 2 for interview guidelines). The interviews were audio-recorded and fully transcribed by an external service provider and also anonymized in this step. 2) The content analysis was computer-assisted using MAXQDA Plus 2020 (version 20.0.3). In order to ensure the reliability and credibility of the analysis we followed the qualitative content analysis based on the approach of Kuckartz [17].

Patient and public involvement

Patients or the public were not actively involved in this research.

Participants and recruiting

The sample is a sub-sample of asplenic patient and doctor participants, who received the intervention and were willing to take part in an additional interview (willingness was queried after participation in the intervention on the phone). Inclusion criteria for patients were met by prior study participation (these were German-speaking, of full age and insured by the cooperating AOK health insurance; see[11]). All interviewees provided written informed consent to participate, including having their interview audiotaped and further processed. They received a 30 € voucher for participation. For reasons of data protection, no personal data was collected.

Patient participants

Patients were selected using a maximum variation sampling approach (purposeful sampling). A maximum variability in terms of their pre-interventional study-specific 'Preventing PSS-score' ('PrePSS-score') was sought. The 'PrePSS-score' indicates patients' adherence to the recommended preventative measures on a scale from 0 to 10 (anti-pneumococcal and anti-meningococcal vaccination, availability of a medical alert card and of an antibiotic supply; for details on development and calculation of the 'PrePSS-score' see[11]), with higher scores indicating greater adherence. With this approach, we expected to explore diverse experiences in implementation as those might differ according to prevention measures taken prior to the study participation.

Selection was performed in two phases. Firstly, all the patients who had agreed to participate were selected successively. After conducting initial N=14 interviews, further patients were purposively selected in an iterative process on the basis of so far unrepresented or underrepresented preinterventional 'PrePSS-score' to obtain maximum variation. Appropriate maximisation was assumed when each possible 'PrePSS-score' (0-10) occurred at least twice. Thus, this approach was also used to determine the minimum number of interviews necessary. Since the values 7, 9 and 10 did not occur among patients who were willing to participate, the range of variation was determined by the actual scores present for this sub-group (for exact frequencies see Table 1).

In total N=31 patients were contacted. As N=6 of them did not provide written consent (N=1 refused participation due to ongoing treatment, N=5 could not be reached), N=25 patients were interviewed. That is 22.7% of all patients (N=110) who received the intervention.

Table 1 *Frequencies of the preinterventional 'PrePSS-score' of the participants*

PrePSS-score (0-10)	**N**	**%**
0	1	4
1	4	16
2	5	20
3	3	12

4	4	16
5	3	12
6	3	12
7	0	0
8	2	8
9	0	0
10	0	0

Doctor participants

Due to low participation willingness and difficulties with accessibility (presumably in part because this study was conducted during the COVID-19-pandemic) a non-purposeful selection procedure was required for the doctors. We took a convenience sample of doctors, i.e. all those who were willing to participate (N=11) were contacted for study participation. Among these, N=8 participated. The remaining N=3 participants were not reachable (N=2) or refused participation due to lack of time (N=1). Participating doctors were the GPs of any of the intervention group patients. Thus, patients and doctors were not chosen in pairs for the interviews.

Interview guideline

The semi-structured interview guidelines for patients and doctors were drafted by N.A und M.B. following Helfferich (2011)[16] and finalised after review by the whole study team. Marginal adjustments to improve applicability were made upon mutual agreement between the interviewers after 14 patient interviews were conducted.

The interview guide for patients was divided into three obligatory main blocks on the topics (a) ′evaluation of the telephone intervention′ (initial question), (b) ′experience in implementing preventative measures′ and (c) ′dealing with sepsis risk′ and (d) a supplementary block addressing the written information material accompanying the telephone intervention. Each question block contained an open-ended obligatory core question that subsumed the key aspects of each topic. Interviewees were to be given the opportunity to freely report on their experiences, specific questions were only posed if a relevant aspect of the core topic was not

proposed by the participants. The interview guide for doctors contained the topics (a) 'evaluation of telephone intervention' (initial question), (b) 'usefulness of the telephone intervention' and (c) a question block addressing the written information material. Overall, the doctor interview guide was more information-orientated compared to the patients' guide, and improvement suggestions were directly requested from doctors. The interview guidelines are attached in supplementary file 2.

Procedure and transcription

Patients and doctors were interviewed individually between January 2020 and April 2021 via telephone by M.B. and N.A. using the developed guideline. M.B. and N.A., both female research assistants and psychologists with experience in counselling and conversation techniques were responsible for the development of the guidelines and the implementation and analysis of the interviews. They were also involved in the development of the manuals for the patient and doctor-directed interventions. Apart from a short telephone contact to arrange the interview date, the interviewers did not know the interviewees beforehand. They introduced themselves as part of the study team responsible for evaluating the intervention. Participants were informed that the study-doctor who conducted the telephone intervention would have no access to recordings or transcripts of individual patient interviews, but only to aggregated, pre-processed data of all the interviewees.

The interview dates were scheduled about 3 months after the telephone intervention. For practical reasons, this period between the intervention and the interview varied between 2.5 and 6.5 months (on average 3.5 months) among the patients. For the doctors, the time period varied between 2.5 and 7.3 months (on average 3.8 months). All interviews were digitally audio-taped in full. No field notes were taken during the interview. The audio recordings were transcribed verbatim by an external transcription service provider. Personal data were pseudonymised before data analysis. Neither transcripts nor results were returned to participants for feedback.

Data analysis

The transcripts of the interviews were analysed using qualitative content analysis largely based on the approach of Kuckartz (2018)[17], which involves both deductive and inductive coding. The chosen multi-level procedure for this study is outlined in Table 2.

Table 2 *Levels of the qualitative content analysis*

Familiarisation stage	Before coding, the entire transcribed text material was read intensively in the process of pseudonymisation and short case summaries were composed.
Inductive-deductive development of the initial coding frame	Based on this familiarisation stage, codes were extracted inductively by N.A. In a next step, additional codes were derived deductively from key topics of the interview guideline, from previous research on barriers that influence patients' adherence to preventative measures [18] and from the underlying theoretical HAPA.
Quota sample trial phase and revision	This initial coding frame was then applied to a quota sample consisting of 20% of the data material (N=5 patient and N=2 doctor interview transcripts), comprising interviews from both interviewers collected at various time points during data collection. In the process of this trial phase, the codes were refined several times through continuous reflection and classified into main and sub-codes.
Entire data material trial phase and team-review	This was followed by the first coding of the entire data material along the so far defined coding frame. In this process, codes were again revised if required, e.g. summarised or differentiated into further sub-codes. In this process a coding guideline was formulated. To ensure intersubjective comprehensibility, the coding frame, the guideline and the coding of individual, randomly chosen interviews were critically reviewed by M.B., M.G. and E.F. and, if needed, slightly adapted to their feedback. This resulted in the final set of six main codes and 11 sub-codes for patients and four main codes and four sub-codes for doctors (for an overview see Table 3 and 4).
Application of the final coding system	This final coding system was then applied to the entire data material by N.A.
Extraction of a code x participant-summary-matrix	In the last step, all the statements of a participant assigned to the same code were paraphrased and the overall findings were extracted from a code x participant-summary-matrix.

Data organisation and analysis was performed using MAXQDA Plus 2020 (version 20.0.3) qualitative data analysis software. Following quantitative descriptive information was calculated using IBM SPSS Statistics (version 27). The entire patient data material to be analysed had covered a duration of about 712 minutes, the data material of doctors circa 148 minutes. The patient interviews lasted between 9 and 75 minutes, with an average length of 28 minutes; doctor interviews lasted between 7 and 30 minutes, on average 18 minutes. The interviews were conducted in German. Code descriptions and quotations taken from the interview transcripts given below are translations from German into English (Table 3 and 4).

Table 3 *Final coding system of patients' interviews*

Main codes	**Sub-codes**
Implementation of preventative measures	
Barriers to implementation of preventative measures	
Perceptions of the intervention	*Evaluation of the telephone intervention and accompanying information material*
	Personal relevance of the intervention
Perceived impact and usefulness of the intervention for implementation	*Implementation of preventative measures*
	Motivation for implementation
	Initiation and maintenance of steps necessary for implementation
	Initiation and maintenance of implementation through prior planning
	Perceived effects of the intervention on the GP

Infection-related risk perception following the intervention	*Cognitive-affective level*
	Behavioural level
Barriers and helpful factors for implementation of preventative measures following the intervention	*Barriers to implementation*
	Helpful factors: social support

Table 4 *Final coding system of doctors' interviews*

Main codes	**Sub-codes**
Barriers to implementation of preventative measures	
Perceptions of the intervention	*Evaluation of the telephone intervention and accompanying information material*
	Relevance of the intervention for own professional work
Perceived impact and usefulness of the intervention for implementation	*Implementation of preventative measures*
	Perceived impact on further medical action
Barriers to implementation of preventative measures following the intervention	

FINDINGS

Patients' interviews

Implementation of preventative measures

Only few patients made reference to prevention measures that had been implemented prior to study participation, with most of them indicating initial approaches and none the full

implementation of recommendations. Patients reported having already received (some or all of) the recommended initial vaccinations. These vaccinations had been administered post-splenectomy by the hospital conducting the splenectomy, after discharge by the GP, a specialist or during rehab and, in two cases of elective surgery, even before the splenectomy. Furthermore, a few patients stated that they had already received a medical alert card for asplenic patients from hospital, which, however in some cases were not filled out completely or not permanently available.

'I have had only, I think, two vaccinations. And then they said that it was done. I then took the list, presented it to him and then I got the rest of the vaccinations.' [ID240216]

Barriers to implementation of preventative measures

Regarding barriers to implement preventative measures, personal, contextual, as well as doctor-attributed factors could be found. The majority of patients mentioned their own insufficient or complete lack of knowledge about the infection risk associated with asplenia and (the need for) corresponding preventative measures. Poor relevant knowledge and failures in implementation were largely attributed to the GP, to the hospital or the rehab centre (or their cooperation), with patients stating that they were either inadequately, incorrectly, incomprehensibly or not at all educated and patients assumed that a lack of relevant knowledge, time or priority by the health care providers were the reasons.

'However, the hospital staff said that everything was okay and that it was possible to live without a spleen.' [ID020314]

Furthermore, comorbidity (mostly cancer) and/or the poor health condition of patients influenced measure implementation as disease-related fears and treatments gave less priority to vaccinations necessitated by the splenectomy or were the reason for their temporary contraindication. Contextual barriers included vaccine supply difficulties and vaccine costs considered not being borne by the health insurance. The results presented below refer to the intervention and to experiences following the intervention.

Perceptions of the intervention

Evaluation of the telephone intervention and accompanying information material

As regards the evaluation of the telephone intervention, a relatively homogeneous picture emerged. Respondents experienced it as pleasant, patient-centred and some mentioned they felt taken care of. The information provided was evaluated as being informative and comprehensible (except for some of the technical terms and abbreviations used). Duration was deemed appropriate and necessary. As to the information material, patients stated they made use of it and some kept it to be able to refer to it at any time. It was rated as informative (in particular the vaccination schedule included) and comprehensible. However, some people clearly expressed the added value of the telephone intervention aligned to the written information material over only having the information material, especially when considering comprehension.

'So that was pleasant for me. I could ask him questions, he calmed me down and, yes, it was understandable.' [ID020314]

Personal relevance of the intervention

Beyond the evaluation of the intervention, its personal relevancy for the participating patients became apparent. Interviewees were appreciative of having received previously unknown or incomplete disease-specific information they rated as subjectively important. They stated that their awareness of risk factors and necessary prevention was formed or increased by the (new) information and some reported they felt safer having been educated now.

'And I have to say, it has also given me a sense of security. And the education was very good, because, as I said before, I had no idea […]' [021310]

Impact and usefulness of the intervention for implementation

Implementation of preventative measures

All the respondents who provided information on immunisation had received the recommended vaccinations since the telephone intervention or had already planned outstanding (or booster)

vaccinations. The medical alert card and the antibiotics for emergency treatment were also mostly permanently available to patients (left in the car, handbag, wallet or mobile phone case), even though there were some failures in filling the alert card in.

'I have got antibiotics for emergency treatment, meantime. I always carry it with me when I go away […] I have the medical alert card with me all the time.' [ID 021311]

Motivation for implementation

Some participants explicitly expressed that the intervention had nudged them to plan, implement or adhere to preventative measures or to demand implementation from their GP.

'[…] that the thought process started for me, what do I have to pay attention to for myself? What do I need to make my general practitioner aware of?' [ID090709]

Aside from that, three interviewees made reference to the influenza vaccination, which they had never received before, but were convinced of its necessity due to the telephone consultation.

Initiation and maintenance of steps necessary for implementation

A large proportion of patients said that they had seen their GP following the telephone intervention to inform him or her of their participation in the study, of required preventative measures and to demand their implementation. Among other things, patients themselves (co-)monitored and organised vaccine supply, vaccination dates and sequence and some partially filled in the medical alert card. In order to keep track of vaccination boosters and expiration dates of the antibiotics, some reported making use of calendar reminders or other notes.

'It's more in the direction of my family doctor that I keep at it, that it continues. There are also problems with the supply of vaccines.[…] And these are currently the issues that are keeping me busy at the moment. I just have to make sure that I get through my vaccination schedule and that I can also tick it off.' [ID090709]

Initiation and maintenance of implementation through prior planning

Some interviewees stated that they followed the individual action plan they had established during the telephone intervention prompted by the study doctor and that they made use of the corresponding worksheet to monitor implemented and pending preventative measures.

Perceived effects of the intervention on the GP

During a consultation following the telephone intervention, patients reported that they perceived their GPs being open to the (new) information and to study (participation). Preventative measures would have taken an unprecedented priority as most doctors supported the implementation by initiating or monitoring the process (e.g. deposited study information, arranged vaccine supplies, reminders about (booster) vaccinations, or completion of the medical alert card).

'So, I have the impression that he's already got this properly on the agenda, to pursue it now and also to take it further. […]. And I attribute this to the conversation with you.' [ID090709]

It has to be mentioned here, that, to the patient's knowledge, some of the GPs had received the telephone intervention for doctors at the time of the patient interview and others had not (yet).

Infection-related risk perception following the intervention

Cognitive-affective level

Some patients indicated that they had (initially) been alarmed, concerned or anxious when receiving (largely) unfamiliar information on the asplenia-related infection and sepsis risk through the intervention. Some described being uncertain about potential risk factors and signs of sepsis as well as about whether they, in case of infection, would react properly. There were also patients who were quite optimistic and unconcerned. Some of these (as well as some of those who stated they were initially concerned) said that they felt safe and prepared to deal with the existing risk thanks to comprehensive education, as well as through preventative measures (to be) taken and knowledge of their efficacy.

'Because before that, it was rather in abeyance. I just read and heard: Yes, blood poisoning, far, far greater risk. […]. However, after that [telephone intervention] it was a bit better […]. So, I don't imagine now my hand suddenly falling off from one second to the next.' [ID021012]

Behavioural level

Besides the cognitive and affective consequences of risk perception, respondents also adapted their behaviour following the intervention. Beyond implementation of the main preventative measures, patients showed precautionary behaviour (i.e. avoiding crowds, keeping their distance from potentially sick people, wearing face masks, being careful about hand-hygiene, avoiding injuries and if needed seeing a doctor sooner) or were alert for symptoms. Some interviewees made direct reference to the current COVID-19-pandemic, which probably had enhanced or induced caution.

'I'm also paying more attention to myself now, even more. And I check every day, is there anything that doesn't belong there? This line or am I warm and have high temperature, […].' [ID120714]

Barriers and helpful factors for implementation following the intervention

Barriers to implementation

For implementation of the targeted preventative measures following the intervention, again personal, contextual as well as doctor-attributed barriers were depicted. The most common personal reason for delayed or prolonged implementation of (booster) inoculations was comorbidity (ongoing chemotherapy or immune treatment), less often mentioned was the personal refusal of the influenza vaccination. Doctor-attributed barriers were poor support in initiating and administering vaccinations, inadequate education about side effects by or confusion about the vaccination sequence. Other barriers were vaccine supply shortages, difficulties in appointment availability and coordination and, in one case, vaccination costs that were assumed to not be covered by the health insurance. Concerning the medical alert card, a few interviewees stated that they were not able to complete it themselves, with some GPs

refusing to help. One patient expressed discomfort at having to manage and carry several (vaccination attesting) documents.

'What I found a pity was that I often presented the medical alert card to my doctor, to my family doctor, but they didn't want it at all... in fact, they didn't even look at it.' [ID041710]

Reasons for not having antibiotics available for emergency treatment were lacking (patient or doctor) conviction or knowledge of individual need, as well as lack of cooperation of the GP. In another case, a patient criticised that her GP did not educate her about the use (including dosage) of the prescribed antibiotic.

Helpful factors: social support

A good relationship, experienced general support, as well as professional advice and care by the GP (and the GP co-workers) were mentioned as a helpful factor in prevention implementation and in coping with their condition by many interviewees. Among other things, it seemed to be of great significance for patients to be able to rely on their GP for (prospective) measure implementation. A large proportion also felt supported emotionally and in prevention implementation by their relatives (thanks to accompaniment to doctor's appointments, for example). Some subjects actively involved family members (in one case also colleagues) by informing them about the disease specifics and preventative measures necessary or already taken (e.g. depository of emergency antibiotic supply).

'My husband also knows about it. Yes, of course, I told him all this too. And he has read everything that he has received. He is also always with me at the doctor.' [ID120714]

Doctors' views

Barriers to implementation of preventative measures

For implementation of the preventative measures prior to study participation, interviewed doctors mentioned both doctor (i.e. own) and health care system-related barriers as well as patient-attributed barriers. Most notably, interviewees described own knowledge gaps or

uncertainties when it comes to asplenia-specific risks, updated vaccination recommendations or the necessity of an antibiotic prophylaxis and some made reference to their minimal routine in the treatment of this patient group. Furthermore, two doctors described deficits at the hospital-outpatient care interface, on the part of the hospital (e.g. misleading information in the discharge letter, lack of raising patients awareness of further out-patient care by GP) as well as the own lack of awareness and assumed patient's failures.

'And that is my mistake, the patient´s mistake, and at the same time the [name of hospital]´s mistake is also present, a hundred percent. All the stops have not been pulled out properly.' [ID072212]

Perceptions of the intervention

Evaluation of the telephone intervention and accompanying information material

The intervention was overall positively evaluated by all the GPs interviewed. The telephone based intervention was viewed as pleasant, instructive and individually-adapted to prior knowledge and the attending patient. The duration of the phone call was viewed as appropriate. Accompanying information material was mostly used and/or deposited for future recourse, content was evaluated as helpful and the scope (with one exception) as adequate. Still, all the GPs gave preference to the telephone consulting over only written information material (in terms of raising awareness and the opportunity to discuss aspects in depth).

'O.k., I found it pleasant, very informative and very individual. He was very responsive to my previous knowledge, I had also read something before.' [ID050610]

Relevance of the intervention for own professional work

Beyond formal evaluation, the GPs addressed the effect of the intervention for their work. They stated that they received subjectively new or up-dated information on asplenic preventative care, classified as reliable (expert knowledge) and helpful for the treatment of their patients. Besides knowledge (-reactivation), they mentioned increased attention to their (further)

patients affected and their own responsibility in implementing and monitoring (e.g. when it comes to booster vaccinations, periodic renewal of antibiotic prescriptions) the precautions.

'So we already knew what we had to do in case of asplenia, but we still hadn't had it on our minds that much.' [ID042812]

Impact and usefulness of the intervention for implementation

Implementation of preventative measures

GPs mentioned preventative measures already implemented or ongoing, mostly in terms of vaccinations. Since the systematic record of their factual implementation was not the aim of this interviews, but rather the experience of it, corresponding responses remained quite vague and rare.

'So she got the medical alert card from you, and, I think I gave her a prescription for the stand-by antibiotic right away.' [ID072212]

Perceived impact on further medical action

Besides implementation of the measures themselves, GPs also named heterogeneous other consequences for their work. For instance, adaption of vaccination schedules and templates for doctor´s letters, storing of patients' asplenia-specific information in the internal system, targeted summoning and broader education of affected patients as well as a more extensive diagnostic work-up in the case of infections.

'When infections occur I become alert and I immediately think, should I treat it with antibiotics now, maybe I need to do a bit more diagnostics than usual?' [ID050610]

Barriers to implementation of preventative measures following the intervention

As regards the implementation of the preventative measures following the intervention, doctors (i.e. own), health care system-related and patient-attributed barriers as well as contextual factors were described by interviewed GPs. Doctor-attributed barriers to vaccination were lack of clarity in the case of concurrent other treatment (e.g. chemotherapy) and inconsistencies in

the vaccination sequence originating from the hospital. At the patient level, comorbid diseases and poor health as well as associated uncertainties posed an obstacle (e.g. refusing immunisation during chemotherapy out of fear). Furthermore, GPs stated vaccination delays due to delivery constraints and named an extra effort of parallel vaccination documentation (medical alert card for asplenia and vaccination certificate).

'Yes, she suddenly got metastases, she has to have chemotherapy again and so she has insisted that she doesn't get any vaccinations. But that would have all worked out, because I would have had her vaccinated earlier if I had gotten the vaccine.' [ID072213]

DISCUSSION

This study explored asplenic patients' and GPs' perceptions of a novel intervention aiming to increase adherence to PSS prevention measures and their experiences in implementation following this intervention by means of a process evaluation. In our sample there were no participants whose answers deviated strongly from the general result. The results of both participant groups therefore provide a relatively homogenous picture and will be discussed conjointly in the following.

The intervention was overall positively evaluated by both patients and GPs. This referred to the intervention framework, comprehensiveness and informative value as well as to its recipient-centeredness, with the telephone based part of the intervention outweighing the written information material provided. Furthermore, the intervention seemed to have a great personal relevance for patients and for the attending doctors' professional work. Both groups reported newly emerged or increased subjective relevant knowledge. This was linked to a sense of security of being well informed in one´s own matter on the part of the patients while GPs mentioned an increased sense of responsibility in the implementation of precautions and several practical implications in the asplenic patients' management.

Even though barriers to initial adherence were not an intended focus of the interviews, most participants referred to it. Both similarities and deviations from relevant studies could be found. Corresponding to previously reported studies, poor relevant patient knowledge were found[4, 5, 7]. Furthermore, comorbid diseases influenced feasibility of the measures, as well as deficits in inter-sectorial communication, the latter also being identified as a key barrier for doctor guideline-conform patient management[4]. However, in comparison to DiSabatino et al. (2017)[8], who described asplenic patients' concerns about the safety of vaccination or scepticism about its benefits as barriers to vaccine prophylaxis, these aspects were not detectable in our interviews.

The intervention, which was theoretically based on the HAPA[12], seemed to be an appropriate strategy to promote asplenic patients' intention to action, action planning and subsequently, to improve adherence to prevention measures. Patients portended they developed risk

awareness, were convinced, and felt motivated and empowered to plan and implement preventative measures or demand their initiation from their GPs. It can be suggested that patients demonstrated self-management behaviour, they presumably did not show before. Risk awareness was manifested on the cognitive-affective level with a tendency of increased anxiousness and mental preoccupation or realistic risk estimation and self-efficacy, as well as in increased health precautionary behaviour and alertness for infection symptoms. Overall, the results indicate that the targeted prevention measures were mostly implemented appropriately and in full following the intervention. Subject to the pending quantitative evaluation, we thus have initial indications that our findings fit in with other research showing the feasibility of HAPA-based interventions in the context of prevention behaviour[i.a. 13].

Our results depict helpful factors and barriers to implementation. As far as helpful factors are concerned, patients alluded to the social support of their GPs, as well as through relatives. Patient and GP reported barriers can be divided into patient-attributed, doctor and contextual or health care system-related factors. Reasons for prolonged or missed vaccination were comorbidities and related treatments (e.g. chemotherapy) and, very rarely addressed, a patient´s personal refusal. Lack of knowledge, support and education on the part of the GPs were also negatively contributing factors. Other reasons were at a contextual level, e.g. vaccine supply constraints, lack of appointment availability or, brought in by GPs, cooperation deficits between hospital and out-patient care. Since the intervention aimed to address evidenced barriers, it corresponds with the expectation that in the overall picture, these were disease-related or structurally given barriers, which could not be addressed by the intervention (e.g. vaccine availability), that would emerge. Therefore, the qualitative study enabled us to go beyond the factors addressed in the quantitative part of the study and take context factors into account, which could be included in future intervention studies and in the actual implementation of the intervention.

The interpretation of all the results must be done bearing in mind that selection bias cannot be ruled out. As participation in the interviews was a voluntary additional effort, participating patients and GPs might be a certain subgroup of study participants who tend to be motivated

or in favour of the intervention and thus may have induced a positive bias in terms of intervention evaluation and reported implementation. Furthermore, selection might have influenced patient-reported barriers (e.g. mostly action-related, rather than personal attitudes opposing prevention measures). Although the patient selection was purposefully aiming at maximum variation regarding their pre-interventional adherence ('PrePSS-score'), it must be further mentioned that very high levels of the PrePSS-score did not occur at all in the sample. However, we argue that this is less severe, as it represents exactly those patients who are the target group of our intervention, as the intervention is not urgent for patients with high adherence scores. Beyond that, it should generally be noted that the prompting of certain issues during the guideline-based interview might have narrowed or limited the answers given. In conclusion, our findings reveal a positive evaluation and a patient and GP perceived benefit of the theory-based intervention, thus fulfilling one requirement for a successful implementation of the intervention. In a next step, the quantitative evaluation of the intervention will be conducted and recommendations for implementation in usual care will be made on the basis of the overall evaluation. In the final stage of the project it is planned to provide the relevant information via our website, congress presentations and publications to GPs and health insurances to encourage them to implement this successful intervention in real health care settings.

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Competing interests

None declared.

Author contributions

Study conception: MG, EF, SR. Development of interview guideline and coding system: NA. Critical review of the interview guideline and coding system: MB, MG, EF. Data collection and analysis: NA, MB. Data interpretation: NA, MB, MG, EF, JC. Drafting and revision of the manuscript: NA. All authors read, contributed to and approved the final manuscript.

Patient consent for publication

Not required. This manuscript does not contain any patients' individual medical information.

Data sharing

Not applicable.

Ethical approval

The study was approved by the Ethics Committee of the Albert-Ludwigs-University Freiburg (No. 380/18, vote from 22 of November, 2018). Informed consent of each patient is obtained in writing prior to participation.

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COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	9
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	1
Occupation	3	What was their occupation at the time of the study?	9
Gender	4	Was the researcher male or female?	9
Experience and training	5	What experience or training did the researcher have?	9
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	9
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	9
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	9
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	6
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	6-8
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	6
Sample size	12	How many participants were in the study?	7-8
Non-participation	13	How many people refused to participate or dropped out? Reasons?	7-8
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	9
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	9
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	6
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	8
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	10
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	9
Field notes	20	Were field notes made during and/or after the inter view or focus group?	9
Duration	21	What was the duration of the inter views or focus group?	10-11
Data saturation	22	Was data saturation discussed?	not applicalble
Transcripts returned	23	Were transcripts returned to participants for comment and/or	9

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	10
Description of the coding tree	25	Did authors provide a description of the coding tree?	11-12
Derivation of themes	26	Were themes identified in advance or derived from the data?	9-10
Software	27	What software, if applicable, was used to manage the data?	10
Participant checking	28	Did participants provide feedback on the findings?	9
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	12-21
Data and findings consistent	30	Was there consistency between the data presented and the findings?	12-21
Clarity of major themes	31	Were major themes clearly presented in the findings?	12-21
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	12-21

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

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Supplemental Material; ANKA et al.

Suppl. Table 1

Interview guideline of patient participants

Welcome and introduction
Introduction of interviewer, aim and procedure of the interview
Interview-questions *(obligatory core questions in bold)*
Evaluation of the telephone intervention (initial question) **Thinking back to the telephone training with the doctor, how did you find that conversation?** How did you feel about the conversation? What do you remember positively/negatively? How was the information? Is there something that would have been helpful for you to know but which did not come up during the phone call? If so, what? How did you feel about the duration of the phone call?
Experience in implementing the preventative measures **How was the implementation of the preventative measures in your daily life?** What went well? What was easy for you to implement? Were there any difficulties in implementing some of the precautionary measures? Was anything cumbersome or difficult to implement? [If yes,] how did that go? What helped you? Did you discuss these steps with the doctor on the phone beforehand? How was that for you? What are the next steps concerning the prevention measures?
Dealing with sepsis risk **You have also talked about the increased risk of sepsis with the doctor. How did that go?** Are you now more concerned about developing a sepsis? If yes, why? Do you feel able to deal with the risk?
Supplementary block: Information material How do you rate the information material that was sent to you by post?
Conclusion and acknowledgement
Do you want to address something we have not talked about yet?

Supplemental Material; ANKA et al.

Suppl. Table 2

Interview guideline of doctor participants

Welcome and introduction
Introduction of interviewer, aim and procedure of the interview
Interview-questions *(obligatory core questions in bold)*
Evaluation of the telephone intervention (initial question) **When you think back to the conversation with the doctor from the university hospital, how did you feel about it overall?** What did you like / less like? Do you have any specific improvement suggestions? How (comprehensible) was the information? Which of the information did you find most (or least) helpful? Is there something that would have been helpful for you to know, but which did not come up during the phone call? If so, what? What did you think of receiving the information on the phone? Do you think the written information (without the phone call) would have been sufficient? How did you feel about the duration of the phone call?
Usefulness of the intervention **Did the information influence your further treatment or education of the affected patient?** If so, how? What information specifically? If not, for what reason?
Written information material How do you rate the information material that was sent to you by post?
Online information The information material included a web address for a website on asplenia. Did you use it and, if so, how?[1]
Expert question **In your view, is there (anything else) that we could improve?**
Conclusion and acknowledgement
Do you want to address something we have not talked about yet?

[1] During the telephone intervention, doctors were referred to an asplenia-website for further information. As this aspect is not relevant for the present work, no corresponding results are reported.