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STUDY PROTOCOLS

StomaCare: quality of life impact after enhanced follow-up of ostomy patients by a home healthcare nursing service—a multicentre, randomized, controlled trial

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Abstract

Aim: A stoma exposes patients to several complications which could impair their quality of life (QoL). In the last decade, the market for stoma therapy in France has evolved, with a significant increase in the activities of home health providers, meeting a need for patient follow-up and companionship. International studies have demonstrated the impact of the stoma therapist (ST) follow-up on the improvement of an ostomy patient's QoL. However, the impact of home stoma nurse management has not been analysed. In this context we would like to assess the added value on health-related QoL from the enhanced follow-up of ostomy patients by STs.

Trial registration NCT05076669.

Methods: This is a randomized, controlled, open, national and multicentre trial (12 centres) which includes patients with an ostomy who benefit from either standard follow-up or from an enhanced and personalized follow-up with, in particular, regular consultations with an ST after discharge. The primary end-point is the 3-month QoL score obtained from the Stoma-QoL questionnaire. The secondary end-points are satisfaction of the care, comparison of QoL scores (Stoma-QoL and EuroQuol EQ-5D) and the economic gains by calculating the consumption of resources between the two arms. There will be a modified intention-to-treat analysis with 6-month follow-up in both study arms.

Discussion: The StomaCare trial will be the first randomized controlled study in France to evaluate the impact on QoL of an enhanced follow-up at home of ostomy patients by an ST.

KEYWORDS
home health providers, quality of life, randomized, stoma, stoma therapist, study protocol

The content of all this protocol is described according to relevant items of the SPIRIT checklist (Standard Protocol Items: Recommendations for Interventional Trials) and numbers in braces in this protocol refer to SPIRIT checklist item numbers [1].

ADMINISTRATIVE INFORMATION

Trial registration {2a}: ClinicalTrials.gov NCT05076669

World Health Organization Trial Registration Data Set {2b}, Table 1

Protocol version {3}: First version 1.0

Funding {4}: Promoter FSK

Authors' contribution {5a}:

All authors contributed to the conception and design of the trial. CdP, MR and JHL drafted the manuscript; all the investigators provided critical revision to the clinical and intellectual content. CdP wrote the study protocol that was reviewed by JHL. DV provided statistical expertise in clinical trial design. Lastly, all authors approved the final manuscript.

Sponsor contact information {5b}

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Email: i.kuhn@fsk.fr

Role of study sponsor and funder {5c}

FSK is a home health provider (HHP). It is the sponsor of the study as well as the provider involved in the delivery of the equipment and the follow-up of the patients through the stoma therapists (STs) and the consultants. As the owner of the data, no use of them can be made without the sponsor's agreement, but the design of the study, the management and analysis of the data are outsourced to an independent company (see below). The sponsor reserves the right to discontinue the trial due to non-inclusion but no changes to the study can be proposed without a joint decision by the sponsor and the coordinating investigator. The sponsor is also responsible for the

TABLE 1 World Health Organization trial registration dataset

Primary registry and trial identifying number	ClinicalTrials.gov NCT05076669
Date of registration	13 October 2021
Secondary identifying numbers	FSK-001
Material support and sponsor	FSK
Sponsor's contact	Ingrid Kuhn; +33 7 61 47 98 25; i.kuhn@fsk.fr
Public title	Quality of life impact after enhanced follow-up of ostomy patients
Scientific title {1}	Quality of life impact after enhanced follow-up of ostomy patients by a home healthcare nursing service employing stomal therapy nurse consultants compared with conventional care: study protocol for a multicentre, open, randomized, controlled trial
Countries of recruitment	France
Health conditions or problems studied	Home healthcare, stomal therapy consultants, ostomy patients, quality of life
Intervention	• Interventional comparator: delivery and enhanced follow-up by FSK (home health provider) in particular, by stomal therapy nurse consultants and patient-relation teleconsultants during in-person or remote appointments in addition to the routine care delivered and prescribed by the sites • Control comparator: routine management of stoma

(Continues)

TABLE 1 (Continued)

Key inclusion criteria	• Aged ≥18 years old • Sexes eligible: both • Temporary or permanent ostomy • Ostomy made less than 10 days ago or during the current hospitalization • Ostomy performed as part of emergency or planned surgery • Patient signed the informed consent
Key exclusion criteria	• Palliative care patients • Participation in another clinical study concerning ostomy care • Patients not affiliated to the French universal health insurance • Patients under guardianship or curatorship • Patients deprived of their liberty (prison or psychiatric care without consent) • Patients with difficulties in understanding or reading French
Study type	Interventional Allocation: randomization Intervention model: parallel assignment Open-label Primary purpose: treatment National and multicentre study Minimal risks and constraints to routine care
Date of first enrolment	August 2023
Target sample size	350 participants
Recruitment status	Recruiting
Primary outcome	Efficacy (time frame 3 months) based on Stoma-QoL specific questionnaire
Key secondary outcomes	• Satisfaction of patient (time frame 3 and 6 months) • Quality of life (time frame 1, 2, 3 and 6 months) based on Stoma-QoL questionnaire and EQ-5D-5L questionnaire • Cost (time frame 3 and 6 months) • Readmission rate (time frame 3 and 6 months)

conduct of the trial, including insurance coverage and reporting of serious adverse events and material vigilance.

Committees {5d}

The scientific committee is composed of the coordinating investigator (Professor Jérémie H Lefèvre), the scientific manager (Professor Morgan Roupret), a stoma nurse (Liliane Jacob), a statistician (Dewi Vernerey), a patients' association (Association Francois Aupetit) and a clinical data manager (Aurélia Meurisse).

Steering committee: The implementation of the study will be realized by the company Sêmeia who will be responsible for the overall management of the study, operational interaction with the investigator centres, the electronic case report form (e-CRF), the design and implementation of the data management plan and analysis.

In each investigator centre a senior lead will be identified and responsible for identification, giving information, obtaining consent, recruitment, data collection and completion of the e-CRF.

In view of the low risks identified above, it was decided not to set up a supervisory committee.

INTRODUCTION

Background and rationale {6a and 6b}

France currently has about 80 000 ostomy patients, 88% of whom have gastrointestinal stomas and 12% urinary stomas [2]. Stoma creation exposes patients to several complications which could impair their quality of life (QoL) [3, 4].

The management of ostomy patients varies between institutions according to how the patient's medical equipment is supplied and whether or not specialized personnel are available. In the last decade, the market for stoma therapy in France has evolved, with a significant increase in the delivery of equipment by HHPs, meeting a need for patient follow-up and companionship. This increased preference of HHPs to use specialist nurses seems to be explained by the added benefits. Early international studies have demonstrated the impact of ST follow-up on the improvement of ostomy patients' health-related QoL [5–9]. However, none of the studies available on follow-ups performed by STs included the French population. Furthermore, the studies show methodological gaps, limited time spans and are based on hypotheses. Finally, in most of these studies, follow-up by an ST consisted mainly of visits while in hospital or during dedicated consultations, but few studies looked at home follow-up by an ST.

Objectives {7}

The main objective of this trial is to demonstrate the effectiveness on the QoL of an enhanced follow-up of ostomy patients by involving an HHP with an ST.

The main secondary objectives are as follows:

- to evaluate patients' satisfaction;
- to analyse the impact of this management on QoL in different targeted subgroups (randomization criteria, temporary or permanent stomas, planned or unplanned surgery);
- to compare health-related QoL longitudinally between the two study arms;
- to investigate clinical and/or demographic factors associated with QoL in ostomy patients;
- to evaluate the financial cost (equipment, products, hospitalization, medication, consultations etc.) of such enhanced follow-up;
- to assess the rate of rehospitalization for ostomy-related complications.

Trial design {8}

It is an interventional, randomized, controlled, open-label, national and multicentre superiority trial with minimal risks and constraints to routine care.

METHODS: ASSIGNMENT OF INTERVENTIONS

Allocation {16}

Randomization (generated by CleanWeb™) will be balanced with a 1:1 ratio between the parallel arms: interventional versus control. It will be realized by minimization and according to (i) the centre, (ii) the type of stoma (ileostomy, colostomy and urostomy/mixed stoma), (iii) the ostomy indication, (iv) gender and (v) the Stoma-QoL score at inclusion divided into four groups: [0–25], [25–50], [50–75], [75–100].

In order to reinforce the random effect and prevent anticipation of the next allocated group, in 20% of cases the software does not use the minimization algorithm and allocates the treatment completely randomly.

Blinding/masking {17}

Given the nature of the intervention, the study necessarily will be open-label. The situation in which the evaluation is conducted by telephone and not by email (see explanations below) will be an exception because in this case the third party collecting the information will be blind to the patient's randomization arm.

METHODS: PARTICIPANTS, INTERVENTIONS, OUTCOMES

Study setting {9}

This is a French national multicentre study, with 12 investigating centres throughout the country (Table 2). These centres will have both gastrointestinal surgery and urology departments and create stomas regularly. They are all expert centres, both public and private establishments.

In addition, data on the management of ostomy patients on discharge from hospital by the investigating centres will be collected: the presence of an ST in the department, organization and number of dedicated ST consultations after returning home, referral of patients to an HHP or pharmacy on discharge and type of discharge (home, hospital etc.).

The study design was defined to meet the outcomes as objectively as possible while ensuring benefit for the patients. This is based on the experience of each of the authors of this study, and the scientific committee whose objective was to consider the complaints and questions of patients in their clinical practice.

Eligibility criteria {10}

The study population will consist of ostomy patients. The study will be proposed by the investigator to patients in the month before the stoma is created and up to 10 days after an operation so as to include emergencies. Patients must provide written, informed consent (see Appendix A).

Inclusion criteria are (i) aged ≥18 years, (ii) patients with a temporary or permanent ostomy made less than 10 days before or (iii) during the current hospitalization (iv) performed as part of emergency or planned surgery, and (v) patients informed orally and in writing via the information sheet and having signed the informed consent.

Exclusion criteria are (i) palliative care patients, (ii) patients participating in another clinical study concerned with ostomy care, (iii) patients not affiliated to a social security regime or to the French universal health insurance (CMU), (iv) patients under guardianship or curatorship, (v) patients deprived of their liberty (prison or psychiatric care without consent) and (vi) patients with difficulty in understanding or reading French.

Interventions: procedure for patients in the interventional group {11a}, Figure 1

TABLE 2 Investigator centres listed

Hospital	Department	Referent investigator	Referent stoma nurse
Saint Antoine Hospital, AP-HP, Paris	Digestive surgery	Pr Jérémie H Lefèvre	Anne Tripon, Dominique Tincelin, Jeanne Sixdenier
Pitié-Salpêtrière Hospital, AP-HP, Paris	Urology	Pr Morgan Roupret	Axelle Pierre-Joseph
Bicêtre Hospital, AP-HP, Kremlin Bicêtre	Digestive surgery	Pr Antoine Brouquet	Corinne Bonneau, Aurélie Courcol
Saint Louis Hospital, AP-HP, Paris	Digestive surgery	Pr Léon Maggiori	Amandine Toutain
Georges Pompidou Hospital, AP-HP, Paris	Urology	Dr François Audenet	Laurence Philibert
Foch Hospital, Suresnes	Digestive surgery	Dr Frédéric Kanso	Elsa Loscot, Sandrine Decamps, Liénor Rafii, Sydonie Baba
Foch Hospital, Suresnes	Urology	Pr Yann Neuzillet	
Lyon-Sud Hospital, Lyon	Digestive surgery	Pr Eddy Cotte	Arianne Deluga
Rangueil Hospital, Toulouse	Urology	Dr Mathieu Roumiguié	Carine Humbert
CHU, Nantes	Digestive surgery	Pr Guillaume Meurette	Agnès Deschamps, Magalie Pottier, Christelle Cathy-Lemoine
CHU Tenon, Paris	Urology	Pr Véronique Phé	Laeticia Quenault
Clinique Saint-Augustin, Bordeaux	Urology	Dr Nam-San Vuong	Katia Cousin
Clinique Esquirol St-Hilaire, Agen	Urology	Dr Xavier Cuvillier	
CHU Tours	Digestive Surgery	Pr Mehdi Ouaissi	Valérie Desvilettes Emilie Houssier

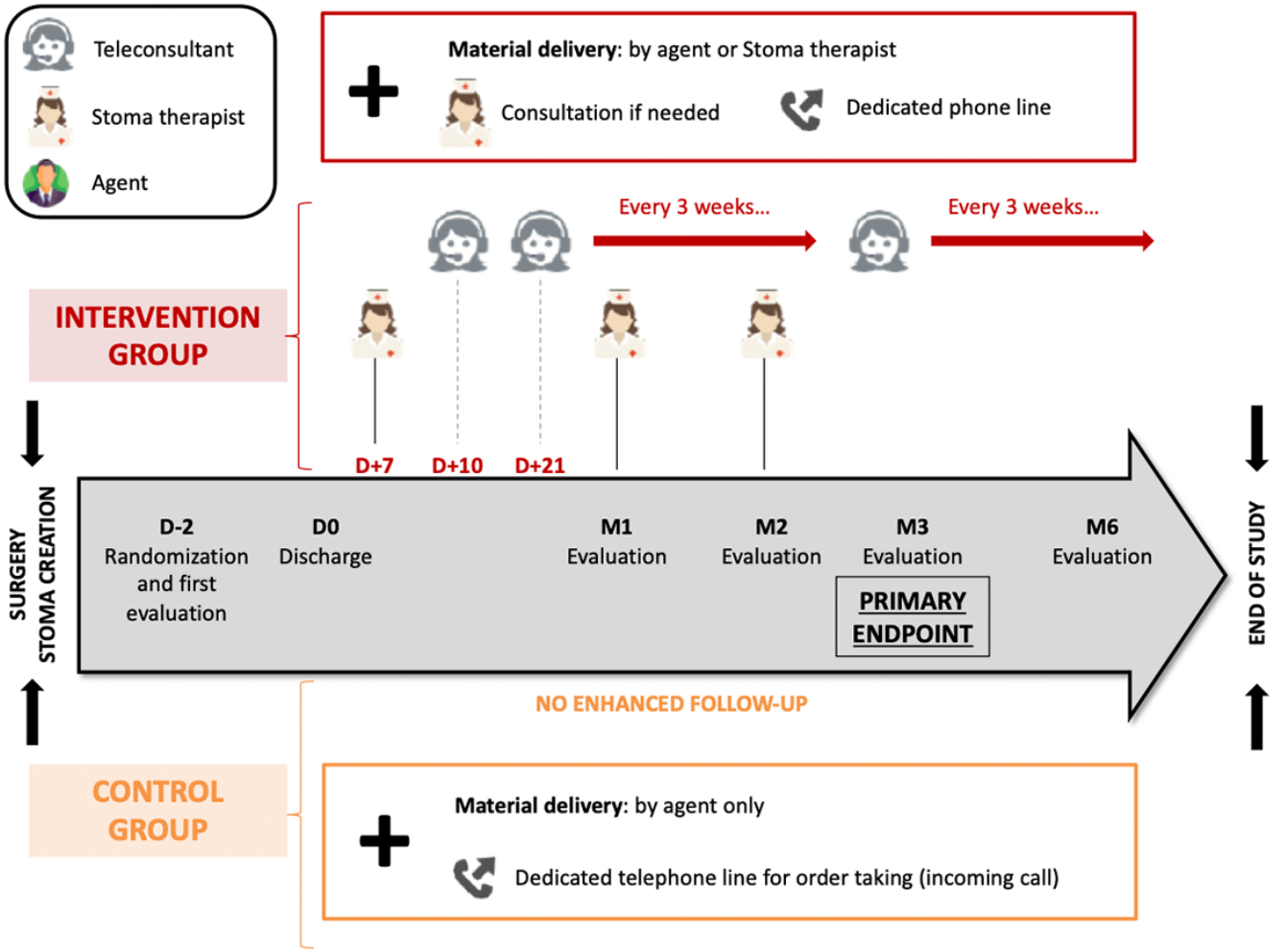

FIGURE 1 Flow chart of the protocol

The HHP FSK personalized support system mobilizes three types of personnel:

1. The agent makes the first delivery of equipment to the hospital or patient's home or another place chosen by the patient. They will be in contact with the prescribing surgeon, to whom they will hand over, in an envelope, the reports produced by the ST following a consultation with the patient.
2. The teleconsultants provide telephone support to patients and are of two types: first, the teleconsultants in the central office who only make outgoing calls to check on patients regularly, help with the ordering and delivery of equipment and request STs if necessary; second, the regional teleconsultants who handle incoming calls from patients to ensure the coordination of the patients' or the central office's requests with the various regional activities of the ST.
3. The FSK ST advisors carry out initial deliveries of equipment, advise the patient on the use of medical equipment and the various treatments, provide liaison with the nursing staff and in particular the home nurses, and carry out physical or virtual consultations proactively or at the request of the patient.

First phase: Delivery of the equipment that will be carried out by an agent or by an ST and will be accompanied by a check of the equipment, an explanation of the services and the provision of a guide to good practice.

Second phase: Continuous and personalized patient support, based on regular telephone follow-up by central patient relations teleconsultants, physical or virtual consultations (via EasyConsult™) and a patient service for handling incoming calls. The telephone follow-up by the teleconsultants will be done on days 10 and 21 and then every 3 weeks, to review the equipment and answer any questions. The ST will carry out physical or virtual consultations on day 7 and at 1 and 2 months. Each consultation (including additional consultations requested by the patient) will result in a report being written and sent to the prescribing doctor. Videos will not be recorded in order to maintain privacy.

Interventions: procedure for patients in the control group {11a}, Figure 1

First phase: Delivery of the equipment to the patient's home, hospital or another place chosen by the patient. This delivery will be carried out only by an agent and will be accompanied by a check of the equipment and the provision of a phone guide regarding renewing equipment orders.

Second phase: Absent. However, there is a phone line that the patient can use to contact the HHP to reorder or change the location of the equipment delivery. Any advice given by telephone will be limited by the competence of the online contact person. In the case of need or problems with equipment and devices, the patient will be asked to contact their healthcare facility again or call for a visit by a nurse at home.

Modifications {11b and 25}

The sponsor is authorized to modify the protocol, in consultation with the coordinating investigator. If necessary, a request for substantial amendments is sent to the Comité de protection des personnes (CPP) (ethics committee) for approval. On receipt of a favourable assessment, the amended version of the protocol will then be sent by the sponsor to all the investigators.

Substantial amendment is defined as an amendment that has a significant impact on any aspect of the research (protection of individuals, conditions of validity of the research, quality and safety of the products tested, interpretation of the scientific documents, procedures for conducting the research), whereas a non-substantial amendment is a minor amendment or clarification with no impact on the conduct of the trial, and will not be submitted to the competent authorities. This will be agreed between the sponsor and the investigator and clearly documented.

The criterion for premature cessation of the trial is early achievement of the recruitment target. The study may also be terminated by the sponsor due to poor recruitment or by a joint decision of the competent authority, the sponsor and the coordinating investigator.

Adherence {11c}

First, we expect to have good adherence by the participants given the low compliance burden and the low risk to the patients in this study. Indeed, the objective of this study is to evaluate an additional service delivered by an HHP as a complement to current practice and not as a substitute for standard care. Nevertheless, to ensure optimal adherence, several elements are proposed:

- Comprehensive information about the research protocol at the time of inclusion with all relevant documents.
- Patients in both groups benefit from an ostomy equipment delivery service and a dedicated hotline provided by FSK in addition to what is usually available to them on their return home (home nurse, consultation with general practitioner, consultation with an ST).
- In addition, in the interventional group, continuous and comprehensive support will be provided both for the supply of equipment and for the provision of nurse/ST advisors.
- To facilitate the fluidity of responses to the questionnaires, they will be sent by email directly to the patient. This avoids the inconvenience of attending consultations or using the postal service. In addition, phone follow-ups will be carried out by a third party who has no knowledge of the assignments to the different arms in order to follow up patients who have not responded to the questionnaires or who are reluctant to use digital tools.

Concomitant care {11d}

Given the low-constraint design of the study, the management of both arms by the same sponsor FSK, and the consideration of major bias in the randomization time, few constraints will be given to the patients. The only clearly identified constraint will be the inability to use any HHP other than FSK for the whole study.

Outcomes {12}

The primary outcome is the 3-month QoL score obtained from the Stoma-QoL health-specific QoL questionnaire [10]. A score on a scale of 20–80 will be obtained after adding the answers to the 20 questions asked with four response modalities: all the time (1 point), sometimes (2 points), rarely (3 points), never (4 points). This score will then be converted to a scale of 0 (worst possible score) to 100 (best possible score).

The secondary outcomes are as follows:

- the satisfaction of care evaluated by a continuous score (between 1 and 10), at 1, 2, 3 and 6 months;
- QoL scores from the Stoma-QoL questionnaire at inclusion, 1, 2, 3 and 6 months and from the EuroQuol EQ-5D-5L questionnaire at 1, 2 and 3 months [10, 11];
- the consumption of resources (equipment, products, rehospitalization, drugs, consultations etc.) and comparing overall and specific costs for each expenditure category between the two arms based on standardized and published price references [12];
- the rate of rehospitalization for complications related to the stoma.

All the proposed outcomes were agreed collectively, taking into account relevant and validated criteria for the patients and the paramedical staff. These criteria are in line with a desire to respond to the complaints and wishes expressed by patients having an ostomy. They were validated by a scientific committee including a stoma nurse and a patients' association (Association Francois Aupetit, AFA) represented by Eric Balez.

Participant timeline {13}, Table 3

Sample size {14}

Randomization of 178 evaluable patients is required (89 in each arm) to demonstrate a mean difference of 5 points on the Stoma-QoL [10] score between the two arms, using a two-sided alpha risk of 5% with a statistical power of 90% and considering a standard deviation of the Stoma-QoL score of 10.2 [10]. An intermediate analysis using the alpha risk expenditure function with the Lan–Demets method (O'Brien–Fleming limits) is planned at 50% of the information fraction (89 randomized patients) [13].

From the 2019 FSK data (not published), the expected drop-out rate at 3 months (death, reinstatement, lost to follow-up) is a weighted average of 43.26%. In order to compensate for these premature discontinuations as well as patient-requested study exits, a margin of 49.11% will be applied to the number of patients needed. To this number, we will also take into account the number of incomplete questionnaires returned. So, the number needed to treat is estimated at 350 patients.

Data collection {18}

The patients will be recruited from the investigating centres after obtaining their consent. After the surgery, the investigators will collect the following information: patient characteristics, demographic

TABLE 3 Study period of the protocol

	Screening	Randomization	Post-allocation				
Time point	**D-10[a]**	**Postoperative time**	**M1**	**M2**	**M3**	**M6**	**In case of SC[b]**
Enrolment							
Eligibility screen	×						
Informed consent	×						
Administrative and baseline data		×					
Allocation		×					
Interventions							
Intervention group		◆———	———	——◆			
Control group		◆———	———	——◆			
Assessments							
Stoma-QoL questionnaire		×	×	×	×	×	×
EQ-5D-5L questionnaire			×	×	×		×[c]
Rate of rehospitalization[d]					×	×	×
Patients' satisfaction			×	×	×	×	×
Cost evaluation					×	×	×
Location of patient (hospital, home etc.)		×	×	×	×	×	×
How to recover the medical material			×	×	×	×	×
Possible assistance in providing care			×	×	×	×	×
Relationship with the health provider			×	×	×	×	×
Relationship with the ST			×	×	×	×	×
Control of the material by the patient			×	×	×	×	×

Abbreviations: D-10, 10 days before surgery; QoL, quality of life; SC, stoma closure; ST, stoma therapist.

[a]Stoma made less than 10 days ago or during the current hospitalization.

[b]Between day − 2 and day + 2 from stoma closure.

[c]Only before 3 months.

[d]Rehospitalization due to a stoma problem.

information, stoma history and Stoma-QoL questionnaire. These elements will be necessary for randomization. The Stoma-QoL will be filled by the patient after stoma creation and just before discharge.

Subsequently, during follow-up, the QoL questionnaire EQ-5D-5L will be asked at 1, 2, 3 months and between 2 days before and 2 days after stoma closure in the event that this will be achieved within 3 months. All other data will be collected at 1, 2, 3, 6 months and between 2 days before and 2 days after stoma closure (Table 3).

Patients in both arms will receive the questionnaire via a web link that will be sent to them by email. It is hoped that an automatic reminder will maximize the response rate. In addition, follow-ups by phone will be carried out by a third party who will be blinded to the assignments in order to follow up patients who have not responded to the questionnaires or who are resistant to the digital tools.

A generalized linear mixed model that can include observations with missing data will be included in the analysis. For tests of significance of differences at 1, 2 and 3 months, only the data available for these dates will be used, so incomplete data will be excluded from these tests.

Data management {19, 21, 23 and 29}

An e-CRF will be used for this study and will only be accessible to authorized persons via a secure internet connection with a login and password. An e-CRF will be completed for each patient included in the study. Data will be collected via the CleanWeb™ application—electronic clinical trial management solution from 'Telemedicine Technologie' society. This solution meets the requirements of the various Best Practices in Clinics (BPC), International Conference on Harmonisation (ICH), 21 Case Report Form (CFR) part 11 (FDA) regulations in terms of identification, authentication, traceability, data flow encryption and data hosting.

Data entry on the e-CRF will be in accordance with the directions provided in the instructions. It is the investigator's responsibility to ensure that the e-CRF is completed, reviewed and approved. Once the pages have been entered and monitored, the investigator will sign them and be responsible for all data entered. All changes to the case report form will be recorded in an audit trail file. Patients will complete the questionnaires via the Cleanweb ePRO system. They will receive a link to enter their answers by email at the different measurement times. The patients' email addresses will be stored in an 'administrative' database which will be

destroyed when the study is deemed complete by the data manager. This 'administrative' database will be hosted on servers different from the data collected via the e-CRF. Once entered, the data will be reviewed by the clinical research officer mandated by the sponsor and/or the data manager.

Data verification and validation will be carried out according to the data validation plan established for the study. The database freeze will be decided by mutual agreement between the study statistician, the principal investigator and the project leader after a review of the data.

The investigator undertakes to accept checks by the sponsor (monitor and/or auditor) or by the inspector of the competent administrative authority. He guarantees access to the source data (medical records, computer files, study documents etc.).

Statistical analysis {20}

Statistical analysis will be performed according to the modified intention-to-treat principle, that is, an intention-to-treat population with at least one baseline Stoma-QoL questionnaire. All statistical analyses will use two-tailed tests and $P \leq 0.05$ will be considered statistically significant.

The variables measured at inclusion will be described, for all patients and in each group, by percentages for the qualitative variables and by the minimum, maximum, means, standard deviations and medians for the quantitative variables. To compare the two groups, a χ^2 test (or Fisher's exact test depending on sample size) for categorical variables will be used and a Student's *t* test for continuous variables. We will use their non-parametric equivalent (Wilcoxon or Kruskal–Wallis test) when the conditions of application are not respected.

Statistical analyses of the data will be carried out using R version 3.6.1 and SAS version 9.4.

Harms and adverse events {20}

The present protocol does not influence the prescription of stoma equipment which will have been freely prescribed by the investigating physician at the time of the patient's inclusion in the study. Thus, the collection of adverse events and any new information that could influence the assessment of the benefit/risk balance follows the European regulations related to material vigilance.

During the study, the consulting STs and client relationship teleconsultants will complete the material vigilance data file with the patient and send it to the investigator and to FSK (materiovigilance@fsk.fr). The investigator will be responsible for declaring a vigilance incident on the official website (www.signalement-sante.gouv.fr) and for reporting the incident to the medical device producer. In the event that the internet website is out of order, an official CERFA form no. 10246 will be completed and sent to the relevant regional administrative authority. A copy of this form will be archived and kept for at least 5 years. Finally, a back-up of all material will be ensured which will itself be quarantined.

Any unexpected death or serious incident or risk of incident related to stoma equipment will be notified to the relevant ethical committees (CPP) by FSK in a timely manner.

ETHICS AND DISSEMINATION

Research ethics approval {24}

- Authorizations from the ANSM (Agence Nationale de Sécurité du Médicament et des produits de santé) and CPP were obtained, approval number ID-RCB: 2021-A00616-35.
- Authorization from the CNIL (Commission nationale de l'informatique et des libertés) was also obtained, registration number 2221807.

Consent to publication {26a}

Patients provide written, informed consent signed after receiving clear and informed advice.

Confidentiality {27}

All study information will be stored securely in restricted areas. All data will be coded with a unique identification number to maintain participant confidentiality (i.e., data management). Participants' study information will not be released outside of the study without the written permission of the participant.

Conflict of interest {28}: None to declare.

Dissemination policy {31}

FSK will own the data and no use or transmission to a third party will be made without its prior agreement. The scientific integrity of the project requires that the data from all centres be analysed study-wide and reported as such. The results will be reported in a publication and submitted to a refereed journal with an editorial board. The rank of authors is defined in advance: JHL, DV, PI, MR according to the number of included patients.

DISCUSSION

This paper describes a protocol for a pilot randomized controlled trial that aims to evaluate the impact of enhanced monitoring of ostomy patients by an HHP, involving an ST, on the improvement of patients' health-related QoL at 3 months compared with conventional follow-up.

Every year in France 16 000 new stomas are performed. The main indications are malignancy (50% of cases), inflammatory and infectious (inflammatory bowel diseases, diverticulitis, colitis etc), traumatic, congenital (Hirschprung disease) and genetic (familial adenomatous polyposis). The frequency of complications in ostomy patients is important and varies from 10% to 80% [14–17]. There are early complications (necrosis, retraction, stenosis with obstruction, bleeding and haematoma, abscesses etc.) [18]. Late complications mainly include peristomal hernia (0–48%) [19], stomal prolapse (10%–20% of colostomy) [20], high output (notably with ileostomy) and peristomal skin complications [21, 22] which affect up to a third of colostomies and two-thirds of ileostomies and urostomies [23] and represent, along with stoma leakage, the earliest complaints by patients. Finally, nearly 30% of ostomy complications will require a surgical intervention. Ostomy management and care are therefore essential

elements in the prevention of complications and in improving QoL [24].

Several studies have shown a relationship between the presence of a stoma and a reduced QoL [25–27]. For example, a study of 391 ostomy patients found that 80% of patients experienced some change in lifestyle, 40% had an alteration to their sex lives, between 35% and 45% of patients had significant anxiety about their stoma and 25% reported being ashamed [28, 29]. Neil et al. showed that each peristomal complication avoided yielded, on average, eight additional quality-adjusted life days over 1 year [30].

Many international studies have demonstrated the impact of follow-up by an ST on the improvement of the QoL of an ostomy patient. In fact, STs play a fundamental role in the education and empowerment of the ostomy patient, in better management and prevention of complications, and in providing psychological support, as demonstrated by Becker's study where 89.3% of ostomates consider that STs are crucial and 70.3% claim to live better with their ostomy thanks to them [6]. The Dialogue Study is a multicentre, open and non-comparative study conducted in North America on 743 patients. QoL was assessed using the Stoma-QoL scale and the condition of the peristomal skin was assessed with the ostomy skin tool. Erwin-Toth et al. observed a 2.1-point increase in the QoL score for patients in regular contact with an ST ($P < 0.001$) and using a double-layer adhesive appliance (over a period of 6–8 weeks) [7]. Marquis et al. in 2003 suggested that the QoL of patients with a stoma is particularly correlated with access to ST care, especially within 3–6 months following surgery [9]. Danielsen and Rosenberg conducted a case–control study of 50 patients and demonstrated an improvement in QoL at 6 months after an ostomy with patients benefitting from educational follow-up ($P < 0.001$) [8].

Finally, many studies agree that follow-up by an ST improves the QoL of patients with a stoma. A recent randomized controlled study demonstrated that telemedicine follow-up by an ST decreased the readmission rate due to complications [31]. Unfortunately, in France, no well-conducted study has evaluated this assumption within the French population. Moreover, access to an ST in France is rather limited and restricted to hospital-based activity.

Through this study, we hope scientifically to demonstrate an improvement in the QoL of ostomy patients by improving access to care through an ST and by providing continuous follow-up after discharge from hospital. At the same time, we expect to see a reduction in stoma-related complications and rehospitalizations in the same population through closer follow-up and earlier management. In the long term, it will be necessary to discuss the implementation of a protocolized follow-up of patients with a stoma within the French healthcare system, with more important and direct access to stoma therapy.

This trial has minimal risks and constraints. The risks to the patient are minimal because they are recruited in hospital and the procedures and functional tests required for the study are performed as part of their usual therapeutic management. On discharge from hospital and throughout the study, care will be administered in the usual way.

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AUTHOR CONTRIBUTIONS

All authors contributed to the conception and design of the trial. CdP, MR and JHL drafted the manuscript, all the investigators provided critical revision to the clinical and intellectual content. CdP wrote the study protocol that was reviewed by JHL. DV provided statistical expertise in clinical trial design. Lastly, all authors approved the final manuscript.

ETHICAL APPROVAL

Authorizations from the ANSM (Agence Nationale de Sécurité du Médicament et des produits de santé) and CPP (Comité de protection des personnes) were obtained, approval number ID-RCB: 2021-A00616-35. Authorization from the CNIL (Commission nationale de l'informatique et des libertés) was also obtained, registration number: 2221807.

DATA AVAILABILITY STATEMENT

Data sharing not applicable to this article as no datasets were generated or analysed during the current study.

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APPENDIX A

Informed consent materials {32}: sample consent form given to the patient for inclusion.

FORMULAIRE D'INFORMATION

STOMACARE

Étude de l'impact du suivi renforcé des patients stomisés par un Prestataire de Santé A Domicile faisant intervenir des infirmiers stomathérapeutes.

Référence ANSM : 2021-A00616-35
Référence CPP : 2021-A00616-35/ SI: 21.04.14.50445

Médecin investigateur coordonnateur :	Promoteur :
Pr Jérémie Lefèvre Chirurgien viscéral et digestif AP-HP Hôpital Saint-Antoine 184 Rue du Faubourg Saint-Antoine, 75012 Paris	FSK 52 Avenue Jean Jaurès, 69600 Oullins

Madame, Monsieur,

Le Dr/Pr ..... vous propose de participer à une étude clinique. Cette étude est menée par la société FSK, Prestataire de Santé A Domicile dont l'activité principale est la livraison à domicile du matériel médical à destination des patients stomisés.

Cette étude vise à évaluer l'impact d'un suivi renforcé des patients stomisés en sortie d'hospitalisation par les équipes FSK.

Vous êtes libre d'accepter ou de refuser de participer à cette étude. Vous pouvez retirer à tout moment votre consentement sans que cela n'affecte votre relation avec votre médecin ou la qualité de vos soins. Votre prise en charge médicale sera alors celle qui est habituellement pratiquée pour votre pathologie.

Veuillez lire attentivement ce qui suit : ce sont toutes les informations qui vont vous permettre de comprendre clairement cette étude clinique, afin d'éclairer votre décision.

Vous pouvez poser toutes les questions que vous souhaitez à votre médecin. Vous disposez également d'un délai de réflexion avant de prendre votre décision. Vous pouvez en parler avec votre famille et votre médecin traitant.

OBJECTIF DE L'ETUDE

Vous allez avoir une intervention chirurgicale conduisant à la création d'une stomie à l'hôpital ou avez récemment été stomisé et vous apprêtez à rentrer à votre domicile ou à être pris en charge dans un établissement de soins de suite et de réadaptation (SSR). L'objectif de cette étude est d'expérimenter de nouvelles modalités de suivi et d'accompagnement des patients stomisés post-hospitalisation par un Prestataire de Santé A Domicile, incluant l'intervention d'infirmier(e) conseils spécialisé(e)s dans les stomies.

Des premières études à l'étranger ont démontré l'impact du suivi par un(e) infirmier(e) stomathérapeute sur l'amélioration de la qualité de vie des patients stomisés. Mais aucune des études disponibles aujourd'hui ne concerne la population française.

C'est pourquoi FSK souhaite mettre en œuvre l'étude visant à évaluer scientifiquement l'impact du suivi des patients stomisés par un Prestataire de Santé A Domicile, faisant intervenir des infirmiers stomathérapeutes.

Qui peut participer à cette étude ?

Tous les patients répondants à ces principales conditions peuvent participer à cette étude :

- Patient adulte (âge ≥18 ans) ayant une stomie programmée dans le mois ou stomisé depuis moins de 4 jours
- Patient informé à l'oral et par écrit via la note d'information et ayant signé le consentement

Afin de pouvoir réaliser l'essai dans les conditions réelles, seront exclus :

- Les patients en soins palliatifs
- Les patients participant à une autre étude en rapport avec stomie
- Les patients non affiliés à un régime de sécurité sociale ou à la CMU
- Les patients sous tutelle ou sous curatelle
- Les patients ayant des difficultés en français

Si vous acceptez de participer à cette étude, vous ne pourrez pas participer à une autre étude clinique en même temps portant sur le suivi des stomisés.

Quelques chiffres clés :

Une dizaine de centres hospitaliers effectuant les stomies participent à l'étude. Il est prévu de recruter 350 patients.

L'étude se déroulera sur 24 mois : une phase d'inclusion de 18 mois puis une phase de suivi des patients sur 6 mois.

DESCRIPTION DE L'ETUDE

Si vous acceptez de participer, vous serez enregistré(e) et votre médecin recueillera quelques informations sur vous, votre maladie et vos traitements. Puis, votre prise en charge sera décidée par randomisation (tirage au sort informatique) :

- Livraison par FSK et suivi standard conformément au plan de soins prescrit par votre médecin.
- Livraison et suivi expérimental par FSK en complément du plan de soins prescrit par votre médecin

Après la randomisation, votre équipe médicale vous remettra une prescription de matériel médical valable pour toute la durée de l'essai et vous accompagnera dans la prise de commande auprès de FSK.

En cas de prescription de soins infirmiers, votre équipe médicale vous remettra également un courrier d'information à destination de l'IDE libéral(e), afin de l'informer de votre participation à cette étude.

Si vous êtes dans le groupe de livraison et de suivi expérimental par FSK :

- Votre matériel médical vous sera livré par FSK soit en établissement la veille ou le jour de sortie soit à votre domicile le jour du retour définitif selon vos préférences et des recommandations vous seront délivrées
- Vous bénéficierez ensuite des services expérimentaux FSK de suivi de votre prise en charge : appels réguliers par des chargés de patientèle FSK, visites assurées par des infirmier(ère)s conseil à distance ou en présentiel selon vos besoins et attentes
- Un questionnaire d'évaluation de la qualité de vie et de satisfaction vous sera envoyé par sms et / ou email cinq (5) jours après votre sortie de l'établissement, puis à un (1) mois, deux (2) mois, trois (3) mois et enfin six (6) mois après votre sortie.

Si vous êtes dans le groupe témoin de livraison par FSK et de suivi standard :

- Votre matériel médical vous sera livré par FSK soit en établissement la veille ou le jour de sortie soit à votre domicile le jour du retour définitif selon vos préférences et des recommandations vous seront délivrées
- Vous contacterez FSK pour le renouvellement de votre matériel médical selon vos besoins grâce à une ligne dédiée à la prise de commande.
- Un questionnaire d'évaluation de la qualité de vie et de satisfaction vous sera envoyé par sms et / ou email cinq (5) jours après votre sortie de l'établissement, puis à un (1) mois, deux (2) mois, trois (3) mois et enfin six (6) mois après votre sortie.

Si vous souhaitez participer à l'étude mais que vous n'êtes pas à l'aise avec les outils numériques, vous pourrez demander à être contacté par téléphone par un Technicien d'Etude Clinique afin de collecter vos réponses. Ce dernier pourra également vous contacter en cas d'absence de réponse aux questionnaires envoyés.

En cas de fermeture de votre stomie temporaire durant l'étude, les questionnaires continueront de vous être transmis.

BENEFICES, CONTRAINTES ET RISQUES

Les risques pendant l'étude ne diffèrent pas d'une prise en charge habituelle et sont ceux du protocole choisi par votre médecin. Ils sont détaillés dans le Plan Personnalisé de Soins qui pourra vous être remis.

Les bénéfices que vous pouvez attendre dans le groupe de suivi expérimental sont une amélioration de votre qualité de vie. Mais, il est possible que vous ne tiriez pas de bénéfice direct de votre participation mais que celle-ci soit bénéfique pour d'autres patients à l'avenir, grâce aux informations qu'elle permettra de recueillir.

Les contraintes liées à cette étude sont minimes puisque la visite d'inclusion se déroulera lors de votre consultation que vous réalisez avec le médecin ayant effectué la stomie et que le suivi se fera à distance.

Vous serez sollicités pour répondre à des questionnaires de qualité de vie et de satisfaction par sms et ou email ce qui peut représenter une contrainte. Elle est cependant limitée car vous serez sollicités cinq (5) fois durant toute la durée de l'étude.

PROTECTION DES PERSONNES

Cette étude clinique a reçu un avis favorable du Comité de Protection des Personnes Sud-Méditérranée II en 2021. Elle a fait l'objet d'une déclaration auprès de l'Agence Nationale de Sécurité du Médicament le 26/02/2021.

FSK a pris toutes les dispositions prévues par la loi sur la protection des personnes notamment la souscription d'un contrat d'assurance auprès de la société Chubb European Group SE, 31 Place des Corolles, Tour Carpe Diem Esplanade Nord, CS 60140, 92098 PARIS LA DEFENSE CEDEX.

Un exemplaire de ce formulaire d'information vous est destiné.

Pour participer à cette recherche, vous devez être affilié(e) à un régime de sécurité sociale.

A l'issue de cette recherche vous pourrez être informé des résultats globaux de ces recherches une fois qu'ils seront disponibles.

CONFIDENTIALITE DES DONNEES VOUS CONCERNANT

Dans le cadre de la recherche impliquant la personne humaine à laquelle FSK vous propose de participer, un traitement de vos données personnelles va être mis en œuvre pour permettre d'analyser les résultats de la recherche au regard de l'objectif de cette dernière.

Votre participation à la recherche implique donc de collecter des données à caractère personnel vous concernant. A cette fin, vos données médicales, seront transmises à la société mandatée par FSK pour réaliser cette étude ou aux personnes agissant pour le compte de FSK. Ces données seront identifiées de façon anonyme et confidentielle par un numéro de code et

vos initiales. Ces données pourront également, dans des conditions assurant leur confidentialité, être transmises au comité de protection des personnes en charge de l'étude ou aux Autorités de Santé Françaises.

Vos données ne seront conservées que pour une durée strictement nécessaire et proportionnée à la finalité de la recherche. Elles seront conservées dans les systèmes d'information du responsable de traitement, du centre dans lequel vous avez été inclus et de la société mandatée par FSK pour réaliser l'étude jusqu'à la publication des résultats de la recherche. Ensuite, vos données seront archivées selon la réglementation en vigueur.

Les données collectées seront conservées chez un Hébergeur Agréé de Données de Santé conformément à l'article L.1111-8 du code de la santé publique, accessible aux seules personnes autorisées.

Conformément aux dispositions de la loi n°78-17 relative à l'informatique, aux fichiers et aux libertés et au Règlement Général sur la Protection des Données (Règlement (UE) 2016/679), vous disposez des droits suivants :

- le droit de demander l'accès, la rectification, l'effacement ou la limitation de vos données recueillies dans le cadre de la recherche. Vous pouvez également accéder directement ou par l'intermédiaire d'un médecin de votre choix, à l'ensemble de vos données médicales en application des dispositions de l'article L. 1111-7 du Code de la Santé Publique
- le droit de vous opposer à la collecte et à la transmission de vos données couvertes par le secret médical
- le droit de récupérer l'ensemble des données vous concernant en vue de les transmettre à un autre responsable de traitement (droit à la portabilité)
- le droit de retirer, à tout moment, votre consentement à la collecte de vos données. Si au cours de la recherche vous souhaitez ne plus y participer, les données vous concernant et acquises avant le retrait de votre consentement seront exploitées par l'investigateur ou son représentant désigné, sauf si vous vous y opposez. Dans ce cas ces dernières seront détruites.

Ces droits s'exercent auprès de l'investigateur ou de son représentant désigné qui vous suit dans le cadre de la recherche et qui connaît votre identité. Vous pouvez également contacter le Délégué à la Protection des Données désigné par FSK en le contactant par mail rgpd@fsk.fr.

Vous disposez également du droit d'introduire une réclamation auprès de la Commission Nationale de l'Informatique et des Libertés – CNIL (autorité française de contrôle des données personnelles).

Nous vous remercions d'avoir pris le temps de lire cette lettre d'information. Si vous êtes d'accord pour participer à cette recherche, nous vous invitons à signer le formulaire de consentement.

CONSENTEMENT DE PARTICIPATION

Etude STOMACARE : Impact sur la qualité de vie d'un suivi renforcé des patients stomisés par un Prestataire de Santé A Domicile faisant intervenir des infirmiers stomathérapeutes conseils comparativement à un suivi conventionnel

Médecin investigateur coordonnateur :	Promoteur :
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J'atteste avoir bien lu et pris connaissance des informations relatives à ma participation à la recherche exposées par écrit sur les pages précédentes et avoir été informé(e) de l'objectif de cette recherche par l'investigateur ou son représentant désigné, de la façon dont elle va être réalisée et de ce que ma participation va impliquer pour moi. J'ai obtenu toutes les réponses aux questions que je lui ai posées.

- J'ai été informé(e) des objectifs, procédures et risques éventuels de l'étude.
- J'ai bien compris les contraintes qui seront les miennes au cours de ma participation à cette recherche qui durera 6 mois
- J'ai eu suffisamment de temps pour réfléchir à ma participation à cette recherche impliquant la personne humaine.
- J'ai bien pris note que je ne pourrai participer simultanément à aucune autre recherche simultanément.
- J'ai été avisé(e) qu'aucune indemnisation n'est prévue pour cette recherche
- J'ai compris que je peux retirer à tout moment mon consentement de participation à cette recherche quelles que soient mes raisons et sans avoir à m'en justifier, sans supporter aucune responsabilité et sans encourir aucun préjudice. J'en informerai simplement le médecin investigateur ou l'équipe investigatrice.
- J'ai bien noté que mon droit d'accès à mes données, prévu par la loi du 6 janvier 1978 relative à l'informatique aux fichiers et aux libertés, s'exerce à tout moment. Je pourrai exercer mon droit de rectification et d'opposition auprès du médecin investigateur ou l'équipe investigatrice. J'ai bien pris note que je pourrai également contacter le Délégué à la Protection des Données (DPO) désigné par FSK en le contactant par mail rgpd@fsk.fr
- J'ai bien reçu une copie du présent document et ai été informé(e) qu'une copie sera également conservée par le médecin investigateur ou l'équipe investigatrice dans des conditions garantissant la confidentialité.

J'accepte que mes données personnelles relatives à mes données de santé soient collectées et traitées par le Promoteur ou pour son compte afin de répondre aux objectifs de la recherche.

J'accepte également que l'ensemble de mon dossier médical puisse être consulté par les personnes habilitées dans le cadre de cette recherche, dans le respect de la confidentialité de mes données et de mon identité.

A compléter de la main de la personne donnant son consentement :	Le __ __ / __ __ / __ __ __ __ Signature du participant
Je soussigné(e) _____ (Nom, Prénom) accepte librement et volontairement de participer à la recherche décrite. Mon consentement ne décharge en rien l'investigateur ou son représentant désigné et le promoteur de l'ensemble de leurs responsabilités et je conserve tous mes droits garantis par la loi.	

A compléter par l'investigateur ou son représentant désigné :	Le __ __ / __ __ / __ __ __ __ Signature de l'investigateur ou de son représentant désigné
Je soussigné (e), Docteur, Monsieur, Madame _____ (Nom, Prénom) confirme avoir expliqué le but et les modalités de cette recherche ainsi que ses risques potentiels. Je m'engage à faire respecter les termes de ce formulaire de consentement, conciliant le respect des droits et des libertés individuelles et les exigences d'un travail scientifique. Nom du service : _____. Tél : _____	

Biological specimens {33}: Not applicable in this study.