Pelvic floor physical therapy in the treatment of chronic anal fissure (PAF-study) study protocol for a randomized controlled trial

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Pelvic floor physical therapy in the treatment of chronic anal fissure (PAF-study): Study protocol for a randomized controlled trial☆

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ABSTRACT

Background: Chronic anal fissure (CAF) is a common cause of severe anorectal pain with a high incidence rate. Currently, a wide range of treatment options are available with recurrence rates varying between 7 and 42%. Pelvic floor physical therapy (PFPT) is a treatment option for increased pelvic floor muscle tone and dyssynergia which often accompanies CAF. However, literature on this subject is scarce. The Pelvic Floor Anal Fissure (PAF)-study aims to determine the efficacy and effectiveness of PFPT on improvement on pelvic floor muscle tone and function, pain, healing of the fissure, quality of life and complaint reduction in patients with CAF.

Methods: The PAF-study is a single-centre, two armed, randomized controlled trial. Patients with CAF and pelvic floor dysfunction are eligible for inclusion. Exclusion criteria include abscess, fistula, Crohn's disease, ulcerative colitis, anorectal malignancy, prior rectal radiation, and pregnancy. A total of 140 patients will be randomized for either PFPT or postponed treatment of PFPT.

The primary outcome is tone at rest during electromyographic registration of the pelvic floor before and after therapy. Secondary outcomes consist of healing of the fissure, pain ratings, improvement of pelvic floor function, complaint reduction and quality of life. Primary and secondary endpoints are measured at 8 and 20 weeks and at 1-year follow-up.

Discussion: Currently, there is a gap in treatment modalities between conservative management and surgery. This manuscript prescribes the rationale, design, and methodology of a randomized controlled trial investigating PFPT as a treatment option for patients with CAF.

1. Background

A chronic anal fissure (CAF) is a longitudinal tear in the anoderm with one or more signs of chronicity including hypertrophied anal papilla, sentinel tag and exposed internal sphincter muscle with symptoms present for longer than 4–6 weeks [1,2]. CAF is a common cause of severe anorectal pain in adults, with a high incidence rate [3] and negatively impacts quality of life [4,5]. Patients with CAF usually experience anal pain, during and immediately after defecation, which may last for several hours. The pathophysiology of CAF is not fully understood, and treatment varies. Conservative management consists of lifestyle advice, high fiber diet and relaxation of the internal sphincter tone with ointment, thus improving blood flow and symptom relief [2,6]. When this conservative treatment fails, the next step can be botulinum toxin A (BTX-A) injections or lateral internal sphincterotomy (LIS). BTX-A is used as an effective treatment modality for anal fissure. It is considered as a minimal invasive procedure with minor adverse effects but has a recurrence rate of 41,7% [7]. The cure rate of LIS is higher than BTX-A and has a recurrence rate of 6.9% [7], however there is a potential risk of incontinence [7–10]. Nevertheless, LIS is the golden standard of care for surgical treatment of CAF [6,11].

A proportion of patients with CAF have concomitant pelvic floor (PF) dyssynergia [12]. Dyssynergia typically present with defecation difficulties consisting of prolonged straining, frequent attempts of evacuation, a feeling of incomplete evacuation and anorectal pain because of incomplete relaxation of the puborectalis muscle [13,14]. Anorectal pain could also result in increased tone (non-neurogenic hypertonicity) of the PF muscles, and this is typically associated with symptoms of

☆ The PAF study group includes the above authors and clinical collaborators at the Proctos Clinic in the Netherlands.

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post-defecatory pain which can last for hours [15,16]. Dyssynergia and/or increased tone of the PF may probably lead to a vicious circle of pain and delayed healing [17]. These PF dysfunctions can effectively be treated with pelvic floor physical therapy (PFPT) including biofeedback therapy and/or neuromuscular electrical stimulation [18–24] and are recommended in current clinical guidelines [25,26]. In addition, PFPT including biofeedback therapy and/or neuromuscular electrical stimulation is a minimal invasive treatment with a low risk of adverse events [25,27–29].

CAF is a debilitating and bothersome condition, particularly because of its recurrent nature. Prolonged persistence of symptoms and recurrence indicate that present treatment modalities are not always sufficient. Currently, there is a gap in treatment modalities between conservative management and surgery. Therefore, we aim to provide a management protocol for PFPT to bridge this gap. We hypothesise that treatment with PFPT in patients with CAF and concomitant PF dysfunction will result in improvement of PF muscle tone and function, pain, healing of the fissure, quality of life and complaint reduction.

2. Methods/design

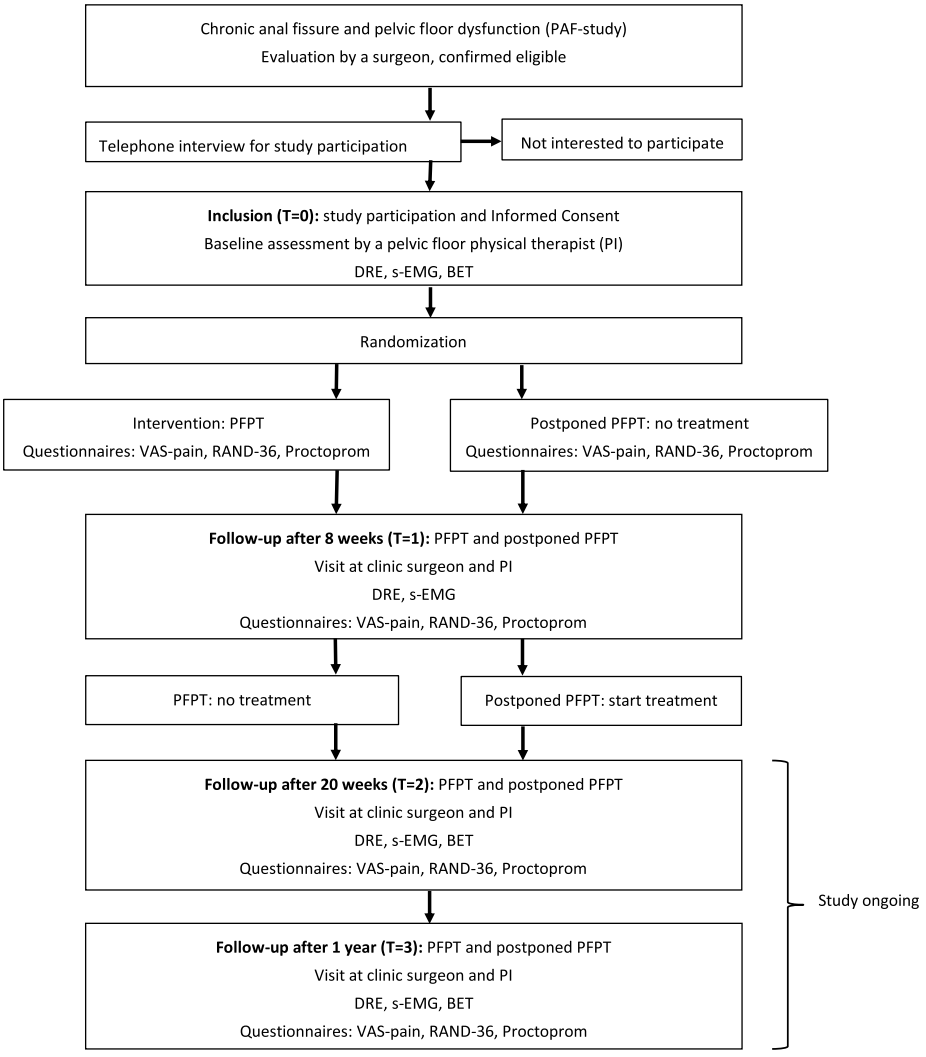
2.1. Objectives

Primary Objective: To establish the efficacy and effectiveness of treatment of CAF and PF dysfunction with PFPT including surface electromyography (s-EMG)- biofeedback.

Secondary objectives: Prevalence of PF dysfunction in chronic anal fissure; - relation between CAF and other PF dysfunctions; - pain reports; - healing of the fissure; - quality of life; - complaint reduction with a proctology specific patient reported outcome measurement.

2.2. Study design

The PAF-study is a single-centre, parallel, randomized controlled trial (RCT). This superiority trial is designed to detect a difference of PFPT including biofeedback and no PFPT at first follow-up. The overall design is shown in Fig. 1. The design involves allocation of all appropriate consecutive patients with CAF and PF dysfunction. Eligible patients will be randomly assigned to an intervention group, which will receive 8 weeks of PFPT or assigned to a control group which will



PI= Principal Investigator; DRE= Digital Rectal Examination; s-EMG = surface-electromyography; BET= Balloon Expulsion Test; PFPT= Pelvic Floor Physical Therapy; VAS = Visual Analog Scale; RAND-36 = 36-short-form health survey

Fig. 1. Study design flow diagram.

receive postponed PFPT.

A complete list of items from the World Health Organization Trial Registration Data Set is provided in Appendix 1.

2.3. Study population

2.3.1. Eligibility

The study population will consist of all patients >18 years old, presenting with CAF and pelvic floor dysfunction.

Inclusion criteria:

- Complaints of more than 6 weeks and all patients failed conservative treatment with ointment, fibers and/or laxatives
- Sufficient understanding of the Dutch written language (reading and writing)
- Able to complete online questionnaires
- Written informed consent

Exclusion criteria:

- Presenting an abscess or fistula
- Crohn's disease or ulcerative colitis
- Anorectal malignancy
- Previous rectal or anal surgery
- Previous rectal radiation
- Pregnancy

2.4. Trial recruitment and consent

Patients will be recruited at a specialized multidisciplinary proctology clinic in the Netherlands. The surgeon, coordinating investigator and/or the principal investigators (PI), a pelvic floor physical therapist, will approach the patient and inform him/her about the study. It is the responsibility of the surgeon and the PI to provide the patient with detailed information, both orally and writing, about the aims and design of the study, as well as the medical procedures involved. If necessary, the patient will have the opportunity to ask all possible questions and receive additional information throughout enrolment in the study. If eligible, the PI will provide the patient with an information letter and informed consent form, explaining the purpose of the study, study design, benefits, and patient risks. According to Good Clinical Practice, a patient is asked for formal consent prior to participation. Patients who decide to participate will bring the signed consent form at first visit with the PI. The PI is assigned for inclusion and informed consent and will be responsible for storing the signed informed consent forms. For those patients who do not consent to participate, the reason(s) for declining will be anonymously recorded in a database.

2.5. Follow-up procedure

Follow-up for all patients will consist of an appointment with the surgeon and PI, at 8 weeks from baseline. Clinical examination will be provided through inspection and digital rectal examination to investigate the improvement of healing of the fissure and PF function. Patients are requested to fill in the validated questionnaires at this timepoint. Patients who were allocated to postponed PFPT will start their treatment after this first follow-up assessment. Patients from both groups will visit the surgeon and PI and fill in the questionnaires at 20 weeks and 1 year follow-up.

2.6. Withdrawal

Patients can leave the study at any time for any reason without any consequences. This will have no consequences for their further treatment. The PI or surgeon can decide to withdraw a patient from the study for urgent medical reasons. Patients will not be replaced in this study after withdrawal.

2.7. Randomization and blinding

After obtaining fully written informed consent, patients will be randomly assigned to be treated with PFPT or assigned to a control group which will receive postponed PFPT (1:1 allocation, random block sizes of 4, 6 and 8). The randomization will be computer generated using Castor EDC (www.castoredc.com). A unique record number will be generated, and the allocation will be disclosed. The PI will not be able to access the randomization sequence. The PI, who will also be involved in the data analysis is not blinded for allocation. The PI will inform the patient about group allocation and follow-up appointments. The PI will also be responsible for communication with the collaborating pelvic floor physical therapist and inform them by telephone call about allocated intervention and other complementary information of the patient. The letter of referral will be sent by a secure online mail system.

2.8. Baseline

2.8.1. Demographics and physical examination

Demographic characteristics will be collected including age, gender, and relevant history.

Clinical data will be collected including previous treatment, duration of symptoms and findings on clinical examination regarding fissure and pelvic floor dysfunction.

To examine PF muscle tone, strength, endurance and relaxation of the PF muscles, a careful functional digital rectal examination will be performed [30–32]. Dyssynergia is detected by rectal examination [33] and balloon expulsion test [34,35]. Besides that, PF muscle tone and function is measured with s-EMG [30,36] with an intra-anal probe (Maple®) [37]. This probe has a matrix of 24 electrodes and is capable of providing electro galvanic stimulation and registering s-EMG-activity nearest to the individual muscles of the PF during diagnosis and treatment [37]. Patients are asked to perform four consecutive tasks: 1-min rest, ten maximum voluntary contractions, one endurance contraction of 30 s and one push effort where the patient is asked to bear down. The Maple® system is validated for its purpose [37,38].

2.8.2. Questionnaires

Patients are asked to fill in three validated questionnaires online. To quantify the average intensity of pain during defecation, a visual analog scale (VAS) will be used on a 11-point scale from 0 (no pain) to 10 (most intense pain) [39].

Quality of life is measured using the RAND-36 Health Status Inventory [40]. The RAND-36 questionnaire entails eight domains of health-related quality of life pertaining to both physical health (physical functioning, role limitations resulting from physical health, pain, general health perceptions) and mental health (emotional well-being, role limitations resulting from emotional problems, social functioning, energy/fatigue). The score for each scale is obtained by the sum of the scores for each item and linearly transformed into a range from 0 to 100 where a higher score denotes a better level of functioning.

The Proctoprom, a patient related outcome measurement was developed by Van der Mijnsbrugge et al. [41], to assess the impact of proctologic complaints on different aspects of a patient's life and evaluates the effect of treatment. This questionnaire consists of 5 items using a scale of 0–10 (0 = no complaints and 10 = maximum complaints), with a maximum score of 50. All items but one (item 4) are mandatory.

An overview of the assessment and questionnaires is shown in Table 1.

2.9. Trial interventions

The description of the intervention follows the Template for Intervention Description and Replication (TIDieR) checklist (Appendix 2).

Table 1
Assessment schedule and questionnaires.

	Baseline	8 wk.	20 wk.	1 year
Digital rectal examination (surgeon/PFPT)	•	•	•	•
Proctoscopy/Endoanal ultrasound (surgeon)[a]	•	•	•	
Surface-electromyography (s-EMG) (PFPT)	•	•	•	•
Balloon expulsion test (BET) (nurse)	•		•	•
Proctoprom	•	•	•	•
Quality of Life (RAND-36)	•	•	•	•
VAS-pain	•	•	•	•

[a] If neccessary

2.9.1. Referral

Patients are referred to an extra mural private practice, preferably nearby patients' home address. The pelvic floor physical therapists providing the treatment are all certified and trained. They all receive the treatment protocol prior treatment and have access to peer consultation when needed. The modalities composing the treatment protocol were selected to reflect clinical practice in the Netherlands.

2.9.2. Interventions

At baseline all patients receive information about the PF and related symptoms, defecation physiology, behavioural modifications and lifestyle advice and continue ointment, fibers and/or laxatives.

The treatment consists of 5 sessions of a mean of 45-min in a period of 8 consecutive weeks. The treatment protocol is comprised of intrarectal myofascial techniques, such as stretching the puborectalis muscle and myofascial release on identified trigger points in the PF to increase flexibility, release muscle tension and improve circulation. Manual techniques are tailored to the patient and based on results and findings of the diagnostic evaluation of the PF at every visit. To gain awareness, patients are taught how to contract and relax the PF muscles and are learned how to incorporate these into daily life. Breathing and PF muscle exercises are combined with surface electromyography (s-EMG)-biofeedback with an intra-anal probe (Maple®) [37]. The sessions are performed to increase awareness and monitor PF (dys)function [21,30,42,43]. Patients with PF dyssynergia learn how to relax the PF during straining. If patients are unable to contract or relax the PF, neuromuscular electrical stimulation will be applied intra-anally during the biofeedback session. The home exercise program incorporates stretching the puborectalis muscle during the application of ointment, and PF muscle - and breathing exercises to improve relaxation. Furthermore, patients use thermotherapy with a heat blanket or sitz baths for relaxation [44]. Additionally, information will be provided with folders and videos to guide the home exercises. Therapy compliance is encouraged because the daily home exercises determine to a great extent the success rate [45]. The collaborating pelvic floor physical therapist will evaluate the patients' compliance of home exercises at every visit.

Patients who are assigned to postponed PFPT will not receive additional treatment besides the use of ointment and fibres/laxatives until first follow-up at 8 weeks after inclusion.

2.9.2.1. Harms. Adverse Events (AE) are defined as any undesirable experience occurring to a subject during the study, whether considered related to the trial procedure or to an already existing condition. All (serious) adverse events, suspected unexpected serious adverse reactions (SUSAR) and any other significant problems are reported to the Medical Ethics Review Committee (MERC) using an online submission system. All adverse events will be described in the final analysis. No adverse events are expected since PFPT including biofeedback and/or neuromuscular electrical stimulation is usual care in our institute. The expected burden for the participants is very low.

2.10. Main study outcomes

2.10.1. Primary outcome

The primary outcome measurement is tone at rest during s-EMG registration of the PF before and after therapy.

Secondary outcomes consist of prevalence of PF dysfunction in CAF; relation between CAF and other PF dysfunctions, PF muscle function before and after PFPT; VAS-pain before-and after PFPT, healing of the fissure (complete re-epithelisation and absence of pain), quality of life (RAND-36) and complaint reduction with a proctology specific patient reported outcome measurement (Proctoprom) before and after PFPT.

The effect analyses adhere to the design of an RCT and measures at baseline, after 8, 20 weeks and 1 year follow-up.

2.11. Statistical analysis

Data are analysed using Statistical Packages for Social Sciences (SPSS, Chicago, II, USA, version 26.0). Descriptive methods will be used to assess quality of data, homogeneity of treatment groups and endpoints. Normality of the data will be analysed with histograms. Data are presented using mean (SD), median (min-max) for the numeric and non-normal variables and frequency (percentages) for categorical variables. A paired *t*-test or Wilcoxon signed-rank test will be used to compare continuous variables within groups. The two-sample *t*-test or the Mann-Whitney-U test for quantitative data and the chi-square test or Fisher's exact test for qualitative data will be performed to test differences between groups. The analysis of covariance (ANCOVA) is used to assess the effect of intervention and to control for baseline measures and confounders. Repeated measure analysis of variance (ANOVA) will be performed for the different time points assessments between groups and interaction between groups and observed time. All *P*-values will be two-tailed and statistical significance will be taken as a *P*-value of less than 0.05. In case of incomplete records, missing data will be imputed using multiple imputation to accommodate intention to treat analysis when more than 5% data is missing. The number of imputations will be defined by the percentage of incomplete patients with respect to the variables of interest. An interim analysis will not be performed for this study.

2.12. Sample size

The primary outcome of the study is the tone at rest during s-EMG registration of PF. In preliminary studies we found a mean of 1.75 in rest, with a standard deviation of 1.75. Based on a slightly conservative standard deviation of 1.8, and a difference to be detected of 1.0, 70 patients in each treatment arm are required to detect a difference of 1.0 between the treatment group and the control group with postponed treatment, with a nominal alpha level of 5% and a power of 90%.

3. Data management and data protection

All medical data will be collected at the clinic before entry into the trial database. After fully signed written informed consent, data collection will be facilitated by case record forms in Castor EDC. Each participant will receive an identification code. Patients' name and other information that can directly identify the patient, will be omitted. The PI will have a decoding list with randomization numbers and patient identification numbers in the investigator site file. Only the coordinating surgeon and PI will have access to the key to the code. All data concerning patients or their participation in this trial will be considered confidential and handled in compliance with all applicable regulations. Data will be stored in a password protected digital database. The data will be archived for 15 years after completion of the study.

3.1. Data safety monitoring

The Committee in Research Involving Human Subjects Leiden approved this study and declared it as a "negligible risk" study and therefore no Data Safety Monitoring Board is needed and no interim analysis or formal stopping rules for the trial are needed to be conducted or formulated. No anticipated harms exist, nor will compensation be provided for trial participation.

3.2. Ethical approval and dissemination

The study is conducted in accordance with the principles of the Declaration of Helsinki, the Medical Research Involving Human Subjects Act (WMO) and the General Data Protection Regulation. The protocol has been approved by the Medical Ethics Review Committee of the Leiden University Medical Centre (P18.090).

Two dissemination meetings were arranged before the study started at the Proctos Clinic with collaborating pelvic floor physical therapists. The meeting provided general background and developed further knowledge in the specialty of anorectal dysfunction. During the pandemic of COVID-19, 3 online meetings were held to mentor these meetings.

Findings of the study will be disseminated in peer-reviewed journals and presented at conferences, whether they are positive, negative, or inconclusive.

4. Discussion

To our knowledge, the PAF-study is the first RCT investigating the efficacy and effectiveness of PFPT with s-EMG biofeedback in patients with CAF.

In the development and implementation of this RCT, several methodological issues were considered such as the design, the duration of the treatment and choice of PFPT modalities. Our treatment protocol consists of a combination of PFPT modalities to promote clinical improvement in patients with CAF which has proven effective in the treatment of pelvic floor disorders [21,24,46].

The distressing and bothersome condition of CAF has a considerable impact on QoL. PFPT already have been proven effective in QoL in patients with pelvic pain and sexual complaints [22,24,47].

To assess the impact of several proctologic complaints on different aspects of a patient's life, the Proctoprom was developed and evaluates disease burden and effect of treatment [41]. The Proctoprom is a valid and reliable tool that is responsive to change and that meets consensus-based standards for the selection of health measurement instruments. The use of this questionnaire will give more rise to burden patients experience in this debilitating problem.

This manuscript presents and discusses the rationale, design, and methodology of a randomized controlled trial investigating PFPT as a treatment option for patients with CAF. Finally, short- and long-term outcome of treatment of CAF using this regime will be described. Findings from this trial will provide a complementary treatment option and could probably become a recommendation in clinical guidelines.

Trial status

During the period March 2020–July 2020 we were not able to recruit patients because of COVID-19. Patient recruitment is completed at the time of submission of this manuscript. It is expected that the study will be completed by July 2022 with the last 1-year follow-up assessment.

Funding statement

No funding of the study.

The authors declare that they have neither competing interests nor conflict of interest.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in the article.

Appendix 1. Items World Health Organization Trial Registration Data Set

Data category	Information
Primary registry and trial identifying number	The Dutch Trial registry; NTR7581
Date of registration in primary registry	12-01-2018
Secondary identifying numbers	Ethical committee, NL65658.058.18 METC-nr. P18.090
Sources of monetary or material support	The Dutch Association for Pelvic Physiotherapy (NVFB)
Primary sponsor	Proctos Clinic, Bilthoven, the Netherlands
Secondary sponsor	Leiden University Medical Centre, Leiden, the Netherlands
Contact for public queries	davr@me.com; + 31622141471; Proctos Clinic, Professor Bronkhorstlaan 10, 3723 MB Bilthoven, the Netherlands
Contact for scientific queries	D.A.van Reijn-Baggen MSc; davr@me.com; + 31622141471; Proctos Clinic, Professor Bronkhorstlaan 10, 3723 MB Bilthoven, the Netherlands
Public title	Pelvic floor physical therapy in patients with chronic anal fissure
Scientific title	Pelvic floor physical therapy in patients with chronic anal fissure: a randomized controlled trial
Country of recruitment	The Netherlands
Health condition or problem studied	Chronic anal fissure
Intervention(s)	*Baseline*: all patients received information about the pelvic floor and related symptoms; -explanation about relevant anatomy and defecation (patho) physiology; -behavioural modifications and lifestyle advice. *Intervention*: 5 face-to-face appointments of a mean of 45-min in a period of 8 consecutive weeks; -intrarectal myofascial techniques; -pelvic floor - and breathing exercises; -surface electromyography biofeedback with an intra-anal probe (Maple®); neuromuscular electrical stimulation intra-anally if applicable *Home exercise programme:*stretching the puborectalis muscle during the application of ointment; -pelvic floor - and breathing exercises; -thermotherapy Control group: no additional treatment besides the use of ointment and fibres/laxatives. Start same treatment protocol at first follow-up (8 weeks after inclusion)

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(*continued*)

Data category	Information
Key inclusion and exclusion criteria	Ages eligible for inclusion: >18 years Sexes eligible for study: both *Inclusion criteria*: Patients presenting chronic anal fissure and pelvic floor dysfunction; -complaints for more than 6 weeks and failed conservative treatment with ointment, fibers and/or laxatives; -sufficient understanding of the Dutch written language (reading and writing); -able to complete online questionnaires; -written informed consent *Exclusion criteria*: Presenting an abscess or fistula; - Crohn's disease or ulcerative colitis; - anorectal malignancy; -previous rectal or anal surgery; -previous rectal radiation; -pregnancy
Study type	Interventional Allocation: randomized Intervention model: parallel assignment Sequence generation: 1:1 allocation, random block sizes of 4,6 and 8 No blinding: the principal investigator, collaborating pelvic floor physical therapists, patients Blinding: surgeon
Date of first enrolment	December 10, 2018
Target sample size	140
Recruitment status	Complete
Primary outcome(s)	Tone at rest during surface electromyographic registration of the pelvic floor before and after therapy.
Key secondary outcomes	Prevalence of pelvic floor dysfunction; -pelvic floor muscle function; -VAS-pain; -healing of the fissure (complete re-epithelisation and absence of pain); -quality of life (RAND-36); - complaint reduction with proctology specific patient reported outcome measurement (Proctoprom)

Appendix 2. TIDieR checklist Pelvic Floor Physical Therapy in chronic anal fissure (PAF-study)

Brief name	Pelvic floor physical therapy in patients with chronic anal fissure: a randomized controlled trial
1. Intervention	PFPT including biofeedback vs postponed PFPT
2. Why	To determine the efficacy and effectiveness of PFPT on improvement on pelvic floor (PF) muscle tone and function, pain, healing of the fissure, quality of life and complaint reduction in patients with CAF.
3. What	Baseline information by PF physical therapist/PI for all patients: Information about the PF and related symptoms, defecation physiology, behavioural modifications, and lifestyle advice (s.e toilet advice, stress reduction). Patients continue fibers and/or laxatives. Patients use ointment 2–3 times a day, before and after defecation and before sleep. Baseline diagnostics by PI for all patients: Digital rectal examination: the patient placed in left lateral position hip flexed at 70° and knees flexed at 90.^{0} After inspection of the anus, the inserted finger is carefully and slowly advanced into the rectum. The resting sphincter tone is assessed in rest and scored as normal, decreased, or increased. PF muscle tone is scored as; normal, decreased, or increased. The patient is asked to squeeze as strong and fast as possible for 10 times, and to squeeze and hold as long as possible (up to 30 s). PF function is scored as; hypertonicity, hypotonicity, coordination, non-functioning and normal. In addition to the finger in the rectum, a hand is placed over the patient's abdomen to assess the push effort. The patient is asked to push and bear down as if to defecate. Push effort of the anal-and PF muscles is scored as relaxation, indifferent or paradoxal contraction.[a] S-EMG measurement; S-EMG is performed with an anal probe (MAPLe®). This is a probe with a matrix of 24 electrodes enabling measuring EMG-signals from the different sides and layers of the PF muscle. The probe is placed intra-anal, the grounding electrode placed on the spina iliaca anterior superior. The patient is asked to perform four consecutive tasks according to a standardized protocol: 1) 1-min rest where participants are instructed to relax and breathe normally; 2) ten maximum voluntary contractions (MVC) where the patient is verbally instructed to perform a short controlled (maximum) contraction for 1 s without contracting the muscles surrounding the PF and relax the PF muscles between the MVC contractions for 3 s; 3) one endurance contraction where the patient is instructed to contract the PF muscles at such a level that they could hold for 30 s, without contracting the muscles surrounding the PF; 4) one push effort where the patient is asked to push and bear down. The investigator is holding the probe to keep it in place. During these examinations, no instructions were given on how to perform a correct PF muscle contraction. From these s-EMG measurements, mean EMG amplitudes per electrode are calculated. The EMG mean values are presented as absolute values (μV). Treatment PFPT: - 5 sessions of a mean of 45-min in a period of 8 consecutive weeks. Different treatment modalities are combined in one session and all treatments are tailored to the patient. - Intrarectal myofascial techniques: stretching the puborectalis muscle and myofascial release on identified trigger points (first 3 sessions for a maximum of 10 min). - PF muscle exercises: contraction and relaxation combined with breathing exercises (first 3 sessions maximum of 10 min) - Breathing exercises and learn how to push (2 sessions), lying down and sitting - Surface electromyography (s-EMG)- biofeedback with an intra-anal probe (Maple®). Relaxation with breathing techniques, maximum contractions and sets of endurance contractions are used to achieve the treatment goals (3 sessions for 15–20 min). - The therapist monitors the adequate relaxation of the PF muscles throughout the sessions. - If patients are unable to relax the PF, neuromuscular electrical stimulation will be applied intra-anally during the biofeedback session (15–20 min about 45 contractions; 35 Hz/250 μsec fade in, fade out 2 s, hold 4–6 s, pause 10–16 s). - If patients are unable to contract neuromuscular electrical stimulation will be applied intra-anally during the biofeedback session (20 min/30–45 contractions; 35 Hz/250–600 μsec; fade in, fade out 2 s, hold 4–6 s, pause 8–12 s). The home exercise program: - Stretching the puborectalis muscle during the application of ointment (2–3 times a day, 5 min); PF muscle - and breathing exercises to improve relaxation (2–3 times a day, 15 min); thermotherapy with a heat blanket three times a day for 15 min, preferable at fixed time points or sitz baths for relaxation. - Information is provided with folders and videos to guide the home exercises. - The collaborating PF physical therapist will ask the patient about the compliance of home exercises and supports correct behaviour at every visit. Changes and improvements are noted in the patient file. Patients who are assigned to postponed PFPT will not receive additional treatment besides the use of ointment and fibres/laxatives until first follow-up at 8 weeks and start with the same treatment protocol.
4. Procedures	Training before the PAF-study started was carried out by an experienced PF physical therapist/principal investigator at a meeting at the Proctos Clinic in the Netherlands. The training provided general background and developed further knowledge in the specialty of anorectal dysfunction. In total 12 of the collaborating PF physical therapists from every part of the country providing the treatment attended the meeting. All PF physical therapists are certified and

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Brief name	Pelvic floor physical therapy in patients with chronic anal fissure: a randomized controlled trial
	trained and have at least 3 years of experience in the field of anorectal problems. They all received the treatment protocol prior treatment and have access to peer consultation when needed. To mentor these meetings, we arranged 3 on-line sessions during the COVID-19 pandemic.
5. Who provided	PFPT is provided by PF physical therapists in the Netherlands. They are registered at the Dutch Society for Physical Therapy in Pelvic Floor Disorders and Pre- and Postnatal Healthcare (NVFB). They are all trained and educated in the performance of invasive techniques, as is used during digital rectal examination, rectal techniques, and biofeedback in men and women. All therapists had training in the use of biofeedback with the Maple®. The PF physical therapist of the Proctos Clinic and principal investigator of the study was responsible for the first diagnostic evaluation of the PF including EMG-measurement, baseline information and follow-up appointments at 8 - and 20 weeks and 1 year.
6. How	Face-to face
7. Where	First meeting and follow-up appointments at 8 -and 20 weeks and 1 year follow-up at the Proctos Clinic in the Netherlands Treatment with PF physical therapist in a private practice, near patients' residence.
8. When, and how much	Baseline and follow- up: at 8, 20 weeks and one year: 4 appointments of 45 min PFPT: 5 sessions in a period of 8–10 weeks (30–45 min) Postponed PFPT: at first follow-up, at 8 weeks after inclusion start treatment with the same treatment protocol
9. Tailoring	The interventions are tailored to the patient based on results and findings of the diagnostic evaluation of the PF at every visit.
10. Modifications	No modification was made
11. How well	Appointments at the private practices are monitored by clinicians delivering the intervention. Monitoring at fixed time points (follow-up) includes an appointment with the surgeon and PF physical therapist/PI at the Proctos Clinic.

PAF-study = Pelvic Floor Anal Fissure-study; PFPT= Pelvic Floor Physical Therapy; CAF = chronic anal fissure; PI = principal investigator; PF=Pelvic Floor; s-EMG = surface electromyography.

[a] During the study the terminology for pelvic muscle assessment was updated in an International Continence Society (ICS) report (2021).

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