Ansøgning til Colitis-Crohn Foreningen (CCF)

Safety and efficacy of capsule-based faecal microbiota transplantation in newly diagnosed patients with inflammatory bowel disease and arthritis: The FRONT Trial (NCT04924270)

MAIN APPLICANT

Maja Skov Kragsnæs (MK), MD PhD, Associate Professor, OUH Frontline Centre for Applied Microbiota and Mucosal Barrier Research (MICARE), Odense University Hospital (OUH) and University of Southern Denmark (SDU): Principal investigator (PI) and project coordinator, responsible for study design, writing the protocol, authority approvals, funding, the overall conduct of the trial, and the manufacturing of FMT capsules.

CORE RESEARCH GROUP AND CO-APPLICANTS

Torkell Ellingsen (TE), MD PhD, Clinical Professor, Head of Research, and Leading physician, Dept. of Rheumatology, OUH Frontline Centre MICARE, OUH and SDU: Co-PI, responsible for study design, authority approvals, funding, and the recruitment of patients with inflammatory arthritis (IA).

Jens Kjeldsen (JK), MD PhD, Clinical Professor, Consultant, Dept. of Medical Gastrointestinal Diseases, OUH Frontline Centre MICARE, OUH and SDU: Co-PI and trial risk manager, responsible for study design, trial conduct, and the recruitment of patients with inflammatory bowel disease (IBD).

Frederik Cold (FC), MD PhD, Consultant and Postdoctoral Fellow, Dept. of Medical Gastrointestinal Diseases, OUH Frontline Centre MICARE, OUH and SDU: Co-PI, responsible for the trial conduct, and the recruitment of patients with inflammatory bowel disease (IBD).

Philip Rask Lage-Hansen (PLH), MD, Head of Research, Departments of Rheumatology and Gastroenterology, Hospital Slagelse: Responsible for recruitment of patients from the Region Zealand.

Anna Christine Nilsson (AN), MD, Chief Consultant, Dept. of Clinical Immunology, OUH Frontline Centre MICARE, OUH and SDU: Responsible for stool donor screening and the FMT capsule production.

INTRODUCTION

The microbiota-inflammation axis

Humans coexist with trillions of microorganisms inhabiting mucosal surfaces. This diverse microbial ecosystem interacts continuously with the immune system through multiple mechanisms, including production of immunomodulatory metabolites, surface molecules (e.g., LPS, flagellin), molecular mimicry, and translocation of microbial products, especially when gut barrier integrity is impaired. Increasing evidence places microbial alterations as a central driver of immune dysregulation and chronic inflammatory disease.(1-3)

Patients with inflammatory bowel disease (IBD) and inflammatory arthritis (IA) consistently display reduced microbial diversity, diminished abundance of short-chain fatty acid (SCFA)–producing bacteria (e.g., butyrate producers), and enrichment of pro-inflammatory metabolic pathways. Such changes have been observed not only during active disease,(4-6) but years before clinical onset,(7, 8) supporting a causal role in disease development. Restoration of microbial diversity and function may therefore represent a powerful add-on therapeutic strategy to conventional immunosuppresive drugs in immune-mediated diseases.(9)

Overlap between IBD and IA

IBD and IA share epidemiological, immunological, microbial, and clinical features.(4) Up to one-third of patients with IBD later develop arthritis, and IA patients have an increased risk of IBD. Both diseases are chronic, often requiring lifelong immunosuppression, including corticosteroids, methotrexate, and costly biological therapies. Importantly, early initiation of disease-modifying treatment improves long-term outcomes, suggesting that the diagnostic window represents an especially modifiable stage of disease pathogenesis. The FRONT trial targets this early phase – prior to substantial tissue damage – where microbiota-modulating interventions may be maximally effective.

Faecal microbiota transplantation (FMT)

FMT transfers a minimally manipulated consortium of microorganisms from a screened donor to a patient with the goal of restoring a healthy microbial ecosystem.(10) FMT is well established for recurrent *Clostridioides difficile* infections,(11) and recent evidence – including Cochrane reviews – suggests it may induce remission in IBD.(12) Our group conducted the world's first randomised controlled FMT trial in IA (the FLORA trial).(13, 14) The intervention induced favourable microbial shifts, including increased faecal butyrate, reduced markers of gut permeability such as serum zonulin, and durable engraftment of donor strains.(14-16) Notably, baseline enterotype predicted long-term clinical response while remission was associated with high bacterial richness and successful long-term colonisation of donor strains,(17) highlighting the therapeutic relevance of microbiota normalisation. These findings strongly support evaluating FMT in the earliest stages of IBD and IA – before chronic immunological self-perpetuation is established.

OBEJECTIVES

Primary objective (A)

To evaluate whether four weekly capsule-based FMTs (cFMT) as add-on therapy to guideline-based first-line immunosuppressive treatment improves patient-reported physical health (SF-36 PCS) at week 8 in newly diagnosed IA and IBD patients.

Secondary objective (B)

To characterise how gut microbiota composition and function, gut barrier integrity, and microbial translocation relate to systemic and intestinal inflammation, disease subtype, baseline prognosis, and treatment response before and after cFMT.

TRIAL DESIGN CONDUCT

Overview

The FRONT trial is a superiority, randomised, double-blind, placebo-controlled, parallel-group, 52-week proof-of-concept study. A total of 200 treatment-naïve adults with newly diagnosed IA or IBD will be enrolled. Participants are stratified by diagnosis and randomised 1:1 to receive:

- **cFMT capsules**, produced from screened donors at the OUH Blood and Tissue Service,(18) or
- **placebo capsules**, identical in appearance.

The intervention is administered once weekly for four weeks. All participants simultaneously initiate standard first-line immunomodulatory therapy according to Danish national guidelines.

Clinical assessments

Comprehensive clinical evaluation is conducted at baseline and at weeks 8, 26, and 52.

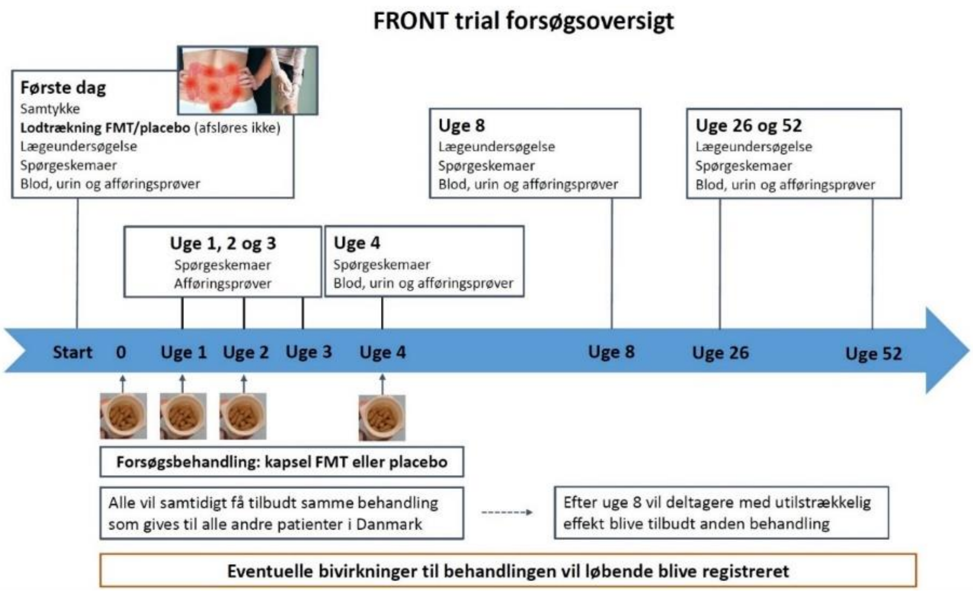
The **primary endpoint** is change in SF-36 physical component score (PCS) from baseline to week 8. The **main secondary endpoint** is the proportion of patients requiring treatment escalation at week 8. Additional outcomes include disease-specific activity responses at weeks 8, 26, and 52, as recommended by the national guidelines for each specific diagnosis, and comprehensive safety assessments. Data are entered into a central REDCap database (eCRF) hosted by OPEN at OUH.

Biological sample collection

Blood, urine, and faecal samples are collected at baseline and at weeks 1, 2, 3, 4, 8, 26, and 52 and stored in the OUH OPEN biobank. Planned assays include:

- Microbiota profiling (shotgun metagenomics)(17)
- Targeted and untargeted metabolomics (16)
- Biomarkers of gut permeability and bacterial translocation (e.g., zonulin) (19)
- Circulating microbial products (20)
- Plasma inflammatory proteomics (15)

These analyses will identify microbial features associated with response to cFMT, disease subtype, and prognosis.



STATISTICAL CONSIDERATIONS

Sample size

A sample size of 200 participants (100 per group) provides >90% power to detect a clinically meaningful 5-point difference in SF-36 PCS change at week 8. Attrition is expected to be minimal during the initial 8 weeks.

Analysis plan

The primary analysis follows the intention-to-treat (ITT) principle. Methods include logistic regression for dichotomous endpoints, ANCOVA or mixed models for continuous outcomes, and adjustment for diagnosis, baseline disease severity, and number of received treatments. For the sensitivity analyses, completer populations at weeks 8 and 52 will be used. Concomitant medications (e.g., antibiotics) are recorded and assessed but not used for covariate adjustment unless predefined.

ETHICAL, REGULATORU AND SAFETY CONSIDERATIONS

cFMT is non-invasive and can be delivered in an outpatient setting without bowel preparation or endoscopy. Donor screening and capsule manufacturing follow the Danish national FMT guideline (10) and comply with EU directives on substances of human origin (SoHO).

The study is approved by:

- The Regional Committee on Health Research Ethics (S-20190141)
- The Data Protection Agency (20/3106)

According to the Danish Medicines Agency, FMT is not classified as a medicinal product, and no clinical trial application is required. The trial is registered at ClinicalTrials.gov (NCT04924270) and conducted in accordance with GCP principles. Patients give informed oral and written consent.

CURRENT STATUS AND FEASIBILITY

By December 2025:

- Six FMT donors have been fully screened and enrolled, producing >200 cFMT products.
- Over 65 patients have been included, with steady recruitment (1–2 participants per week), this in collaboration with partners at Svendborg Hospital, Hospital Lillebaelt (Vejle), and Slagelse Hospital.
- Funding from Sygeforsikringen "danmark" (DKK 2.5M), the AP Møller Foundation (DKK 100,000), the Danish Psoriasis Foundation (DKK 50,000), and the OUH Frontline Centre MICARE (DKK 1.5M) fully supports the clinical component.

At the current inclusion rate, recruitment of all 200 patients will be completed by 2027, with final follow-up in 2028. Laboratory analyses will be conducted in 2027/28.

The requested **DKK 100,000 from the Colitis–Crohn Association** will support:

1. **Patient transportation reimbursement** for participants living outside Funen, especially from Region Zealand.
2. **Co-funding microbiota analyses**, enabling detailed characterisation of donor strain engraftment and microbial predictors of response.

EXPECTED CLINICAL IMPACT

The FRONT trial is the **first randomised, double-blind trial worldwide** to evaluate repeated capsule-based FMT combined with standard immunomodulatory therapy at the earliest phase of IBD and IA. By intervening at diagnosis – before chronic immune activation becomes entrenched – the study examines whether microbiota normalisation can:

- Increase remission rates
- Reduce treatment escalation
- Improve long-term outcomes
- Provide microbial biomarkers predictive of treatment response
- Prevent disease chronification

If successful, the trial will support integrating microbiota-modulating strategies into clinical guidelines and pave the way for personalised, microbiota-based interventions in IBD and IA.

The study has strong potential to contribute transformative evidence to international microbiota research and to directly benefit Danish patients by improving early disease management, reducing need for biological therapy, and enhancing long-term quality of life.

On behalf of the project team,

Maja Skov Kragsnæs, MD PhD

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Lægmandsrapport

Titel: *FRONT-studiet: Kan en sundere tarmflora forbedre tidlig behandling af IBD og inflammatorisk artrit?*

Baggrund: Mennesker lever i tæt samspil med billioner af bakterier og andre mikroorganismer, som især findes i tarmen. Denne tarmflora har stor betydning for immunsystemet. Når balancen i tarmbakterierne forstyrres – fx færre gavnlige bakterier og flere betændelsesfremmende – kan det være med til at udløse eller forværre kroniske sygdomme som inflammatorisk tarmsygdom (IBD: colitis ulcerosa og Crohn's sygdom) og inflammatorisk artrit (IA). Både IBD og IA er kroniske sygdomme, som ofte kræver langvarig behandling med immundæmpende medicin som prednisolon, methotrexat og biologiske lægemidler. Mange patienter med IBD udvikler senere artrit, og omvendt har IA-patienter øget risiko for IBD. Nyere forskning tyder på, at ændringer i tarmfloraen opstår tidligt i sygdomsforløbet – nogle gange flere år før diagnosen. Det gør de første måneder efter diagnosen til et særligt vigtigt tidspunkt at gribe ind.

Hvad er FMT?

Fækal mikrobiota-transplantation (FMT) betyder, at man overfører en sund og nøje screenet tarmflora fra en donor til en patient – i dette studie via kapsler. FMT bruges allerede med stor succes mod infektioner med *Clostridioides difficile*, og der er stigende dokumentation for, at metoden også kan hjælpe patienter med IBD. Vores forskergruppe har tidligere vist, at FMT kan påvirke tarmens bakteriesammensætning, tarmbarrieren og immunsystemet hos patienter med inflammatorisk artrit.

Formålet med FRONT-studiet: FRONT undersøger, om fire ugentlige FMT-kapsler som tillæg til standardbehandling kan forbedre patienternes fysisk helbred og sygdomsaktivitet i den tidlige fase af IBD eller IA. Studiet har to hovedmål:

1. At se, om FMT kan forbedre patienternes helbred efter 8 uger (målt ved SF-36 spørgeskemaet [patientens oplevelse] samt behov for at intensivere behandlingen [lægens vurdering]).
2. At forstå, hvordan tarmfloraen, tarmens barriere, betændelsesmarkører og mikrober i blodet hænger sammen med sygdom og behandlingsrespons.

Hvordan foregår studiet?

200 ny-diagnosticerede med IBD eller IA deltager. De bliver tilfældigt fordelt til enten:

- **FMT-kapsler** fra godkendte, screenede donorer, eller
- **Placebo-kapsler**, som ligner FMT men ikke indeholder bakterier.

Alle starter samtidig deres almindelige førstevalgsbehandling efter danske retningslinjer. Patienterne følges i ét år med kliniske undersøgelser efter 8, 26 og 52 uger. Der indsamles blod-, urin- og afføringsprøver til avancerede analyser af tarmbakterier, betændelse og tarmbarriere.

Hvorfor er dette vigtigt for patienter?

FRONT-studiet undersøger, om man ved at genoprette en mere "sund" tarmflora tidligt i forløbet kan:

- forbedre chancen for remission
- mindske behovet for stærkere medicin
- reducere betændelse i både tarm og led
- skabe mere varige forbedringer i livskvalitet
- identificere biologiske markører, som tidligt kan fortælle, hvem der vil have gavn af behandling

Dette kan føre til mere målrettet og personlig behandling af både IBD og IA.

Status og betydning for danske patienter

Studiet er i god fremdrift: Mere end 65 patienter er inkluderet, og finansiering til den kliniske del er sikret. Støtten fra Colitis-Crohn Foreningen vil gå til transportgodtgørelse for patienter bosiddende uden for Fyn og til vigtige mikrobiota-analyser, som kan afsløre hvilke bakterier, der koloniserer tarmen efter FMT. Hvis FRONT-studiet viser positive resultater, kan FMT blive en fremtidig del af behandlingen tidligt i sygdomsforløbet. Det kan betyde færre opblussen, mindre behov for biologisk behandling og bedre livskvalitet for patienter med IBD og IA.

Budget

FRONT TRIAL BUDGET (DKK)	2026	2027	2028	Ansøgt fra CCF 2026-28	Bevilliget fra andre fonde*
VIP løn for MSK og FC	750.000	750.000	300.000		1.800.000
TAP løn forskningssygeplejersker og bioanalytiker	200.000	150.000	50.000		400.000
FMT kapselprodukter	200.000	100.000			300.000
Etablering af biobank og forsendelse af prøver til ind- og udland	150.000	125.000	75.000		350.000
Data management, statistisk assistance og artificial intelligence		10.000	15.000		25.000
Transportgodtgørelse til patienter bosiddende uden for Fyn	50.000	35.000	15.000	50.000	50.000
Biobanksanalyser (herunder bakterieanalyser)			750.000	50.000	
Overheads 5% OUH Forskerservice (administrering af bevilling)				5000	97.415
I alt	**1.350.000**	**1.170.000**	**1.205.000**	**105.000**	**3.022.415**

*Den eksisterende finansiering fra Sygeforsikringen "danmark" (2,5 mio. kr.), A.P. Møller Fonden (100.000 kr.), Psoriasisforeningen (50.000 kr.) samt OUH Frontline Centre MICARE (1,5 mio. kr.) har muliggjort inklusionen af de nuværende 65 patienter og dækker fuldt ud den resterende kliniske del af projektet fra 2026-28. Psoriasisforeningen har givet 50.000 kt. i støtte til transportgodtgørelse til patienter, der deltager i forsøget, men f.eks. bor på Sjælland.

Det ansøgte beløb på 100.000 kr. (+ 5.000 kr. i overhead til OUH) fra Colitis–Crohn Foreningen vil dække følgende projektrelaterede poster:

1. **Transportgodtgørelse til deltagere bosat uden for Fyn, særligt fra Region Sjælland.**

   Hver deltager vil blive bedt om at møde 8 x på OUH ifm. deres deltagelse i FRONT. For deltagere bosiddende uden for Fyn (f.eks. Sjælland), vil vi anmode om at dække deres udgifter til en togbillet og/eller kørsel i egen bil (inkl. brogift svarende til 2x 205 kr pr. FRONT besøg). I gennemsnit vil de samlede udgifter pr. deltager løbe op i ca. 4000 kr. Således forventer vi at kunne hjælpe 12-15 patienter med transportgodtgørelse ifm. deres deltagelse i forsøget. Denne støtte vil have stor betydning for, at vi kan opretholde (eller endda øge) den nuværende inklusionsrate og give patienter bosiddende uden for Fyn mulighed for at deltage i FRONT uanset deres private økonomiske forhold.

2. **Medfinansiering af bakterie-analyser, som muliggør detaljeret karakterisering af donorstammers kolonisering og mikrobielle markører for behandlingsrespons.**

   Støtte fra CCF til denne post vil være vigtig i vores bestræbelser på at opnå en større bevilling (DKK 700.000) til dette formål fra enten DFF, Novo Nordisk og/eller andre fonde med fokus på personaliseret behandling og afdækning af mekanismerne for de mulige gunstige effekter af FMT til patienter med IBD og IA.

OUH ForskerService har godkendt ovenstående budget. Hvis denne ansøgning imødekommes af CCF, vil OUH ForskerService stå for at administrere bevillingen.

Forskningsleder indenfor området: Klinisk professor Torkell Ellingsen (torkell.ellingsen@rsyd.dk)

Signaturside vedrørende ansøgning til Colitis-Crohn Foreningen (CFF)

Titel: *FRONT-studiet: Kan en sundere tarmflora forbedre tidlig behandling af IBD og inflammatorisk artrit?*

Ansøger: Maja Skov Kragnsæs

Samlet ansøgt beløb: DKK 105.000

Projektperiode: 1. januar 2026 til 31. december 2028.

FORSKNINGSLEDER

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CHEFLÆGE

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EDUCATION

2021	**PhD in Medicine, University of Southern Denmark (SDU)** "Psoriatic Arthritis and Faecal Microbiota Transplantation (FMT): Safety, Efficacy and Patient Perspectives", SDU, Denmark. Main supervisor: Prof Torkell Ellingsen.
2013	MSc in Medicine, Aarhus University

CURRENT AND RECENT POSITIONS HELD

2024 -	**Associate Professor, Dept. of Clinical Research, SDU (termination date: 31.3.2029)**
2021-	**Medical doctor, Dept. of Rheumatology, Odense University Hospital (OUH)**
2021-24	Postdoctoral researcher, Dept. of Rheumatology, OUH.
2016-20	PhD fellow, Research Unit of Rheumatology, OUH and SDU
2014-15	1st year of specialist training (internal medicine), Silkeborg Regional Hospital

SCIENTIFIC FOCUS AREA

My research focuses on the interplay between the human microbiota and autoimmune and chronic inflammatory diseases (CIDs) to guide translation into clinical practice. Specifically, whether manipulation of microbial alterations and "leaky gut" can be relevant future treatment targets in CIDs, and whether microbiota characteristics and blood-based markers of "leaky gut" can be used as diagnostic biomarkers and/or drug response predictors. The applied research methodologies include randomised controlled trials (RCTs), observational studies, and laboratory investigation performed on biological specimens, qualitative approaches, systematic reviews (meta-analysis), and epidemiological/register-based studies.

AVADEMIC AND RESEARCH ACHIEVEMENTS/AWARDS

2021	**Best Clinical Research Award at the European Alliance of Associations for Rheumatology (EULAR) Congress (OP0010)**
2019	**Second place in the public research competition "Et Sundere Syddanmark 2019"** **Prize award: DKK 600,000.**
2013	The Danish Rheumatism Association Student Research Award. Prize ward: DKK 10,000.

SELECTED INTERNATIONAL PRESENTATIONS

2025	**Chair and organiser of the MICMUC onsite meeting** at the EULAR Congress, Barcelona
2024	Annual EULAR Congress, **oral presentation**, Vienna
2024	**Chair and organiser of the MICMUC onsite meeting** at the Annual EULAR Congress, Vienna
2024	**Invited speaker at the British Society for Rheumatology Conference, Liverpool 2024**
2023	**Invited speaker**, ENDOTARGET symposium, Santiago de Compostela, Spain 2023
2023	**Chair and organiser of the MICMUC onsite meeting** at the Annual EULAR Congress, Milan
2023	**Invited speaker**, **International Genetics of Ankolysing Spondylitis Consortium**, Naples
2022	**Invited speaker**, Symposium on gut microbiota modulation in health and disease, Cph
2021	Annual EULAR Congress, **oral presentation** and **best project award winner** (OP0010)

INTERNATIONAL NETWORKS

2022 -	**Initiator and leader of the research collaboration on Microbiota and Mucosal Barrier Research in Rheumatic and Musculoskeletal Diseases endorsed by the European Alliance of Associations for Rheumatology Oct 2022 (the EULAR MICMUC group);** with >37 members from research institutions across Europe, Australia, Japan, and USA.
2019 -	Member of the NorMic and the FMT Nordic Trial Alliance

PRINCIPAL INVESTIGATOR AND PROJECT LEADER ON THE FOLLOWING ONGOING PROJECTS (2025 -)

PI OUH Frontline Centre for Applied Microbiota and Mucosal Barrier Research (start date: 01.07.2025)

Double-blind, randomised, controlled trial of capsule FMT in arthritis and IBD (FRONT; NCT04924270)
Co-PI: Professors Torkell Ellingsen and Jens Kjeldsen. Anticipated end date: 31.12.2028.
Planned collaboration with international partners in relation to the exploratory biobank analyses.

Systematic review and meta-analysis on microbiota-targeted interventions in rheumatic diseases (MICAIRE; CRD42025644244). Anticipated end date: 31.12.2026.
International collaborators: 37 international colleagues from Europe, Australia, and the United States.

LEADERSHIP AND PROJECT MANAGEMENT COURSES

2023	Educational course for associate professors, SDU
2022-23	Increasing value by reducing waste in research, OUH

SUPERVISOR RESPONSIBILITIES

2024-	**Co-supervisor for one Ph.D. student (SDU)**
2024-25	**Main supervisor for one undergraduate student (Katrine A Hovmand):** Two peer-reviewed publications.
2018-23	Co-supervisor for five undergraduate students

BOARDS, COMMITTEES, AND SCIENTIFIC SOCIETIES

2019-	Member of the Danish Association of Clinical Immunology (DSKI)
2018-20	Member of the Assessment Committee of OUH's Research Council
2015-	Member of the Danish Association of Rheumatology (DRS)
2013-	Member of the Danish Medical Association

REVIEWER FOR INTERNATIONAL SCIENTIFIC JOURNALS

Reviewer for >5 international journals including *BMJ Open*, *Therapeutic Advances in Musculoskeletal Disease*, *Gut Microbes*, and *Joint Bone Spine*.

GRANT RECORD AS MAIN-/CO-APPLICANT BEING PRIMARY GRANT WRITER

Total amount 2015-2025: DKK 13,987,000 (> 70% from external sources)
As main applicant: DKK 3.787.000. As co-applicant being primary grant writer: DKK 10.200.000

TEXTBOOKS

Co-author **"Basisbog i Medicin og Kirurgi" 7th ed** (ch. on rheumatic diseases); *in-progress*
Co-author **"Klinisk ernæring" 6th ed** (ch. on rheumatic diseases). 2023. ISBN: 9788702354058.

SELECTED PUBLIC AND SOCIAL MEDIA PRESENTATIONS

2025	**Dagens medicin**: tarmbakterier-kan-have-betydning-for-effekten-transplantation-med-afforing/
2025	**Videnskab.dk: kost-og-affoering-kan-maaske-hjaelpe-psoriasispatienter**
2024	**Magasinet Helse** (Nov/Dec 2024)**:** Folk med autoimmune gigtsygdomme kommer for sent i behandling – sammenhæng mellem tarmbakterier og gigt
2024	**FMT in arthritis: 'just the beginning'** (thelimbic.com), online interview
2019	**Public research competition**, TV broadcast. "Et Sundere Syddanmark 2019"

Maternity leaves in 2016, 2018, and 2021

ORIGINAL RESEARCH PEER-REVIEWED PUBLICATIONS AND CORRESPONDANCES

Total: 17
Last authorships: 1 original peer-reviewed paper
First authorships: 10 original peer-reviewed papers + 2 correspondances.
H-index based on first- and last authorships: 7 (Scopus; 10 Dec 2025). **Citations**: 276

1. MS. Kragsnaes, Benoît Thomas P. Gilbert, Bjørk Khaliqi Sofíudóttir, Christopher Michael Rooney, Sebrina Maj-Britt Hansen, Daniele Mauro, Benjamin H. Mullish, Anne-Sophie Bergot, Kulveer Singh Mankia, Niti Goel, Gunnstein Bakland, Peter Holger Johnsen, Jesus Miguens Blanco, Simone Li, Emilie Dumas, Philip Rask Lage-Hansen, Carlijn Wagenaar, Ghaith Bakdash, Mat Robinson, Karsten Kristiansen, Julian R. Marchesi, George Schett, Mario M. Zaiss, Mine Orlu, Dennis McGonagle, Dirkjan van Schaadenburg, Jose U. Scher, Dirk Elewaut, Maxime Breban, Peter Tugwell, Axel Finckh, Francesco Ciccia, Martin A. Kriegel, Claire Daien, Torkell Ellingsen, Robin Christensen, EULAR Study Group MICMUC. **Efficacy and safety of microbiota-targeted therapeutics in autoimmune and inflammatory rheumatic diseases: protocol for a systematic review and meta-analysis of randomised controlled trials**. *BMJ Open* 2025 Vol. 15 Issue 12 Pages e101593. DOI: 10.1136/bmjopen-2025-101593

2. Hovmand KA, Jochumsen EA, Kjeldsen J, Holm DK, Nilsson AC, Justesen US, **Kragsnaes MS**. **Impact of storage conditions on live bacteria in partially processed faecal microbiota transplantation products using culturomics**. *Lett Appl Microbiol.* 2025 Nov 8;78(11):ovaf126. doi: 10.1093/lambio/ovaf126.

3. Qin P*, **Kragsnaes MS*,** Holm DK, Horn HC, Nilsson AC, Kjeldsen J, Kristiansen K, Ellingsen T. **Clinical Significance of Gut Microbiota Community Types for Long-term Response to Fecal Microbiota Transplantation in Patients with Psoriatic Arthritis**. *Arthritis Rheumatol.* 2025 Aug 15. doi: 10.1002/art.43359. Epub ahead of print. PMID: 40814761. ***MSK and PQ share first authorship**. *Citations: 1*

4. Dürholz K, Ehnes, Linnerbauer M, Schmid E, Danzer H, Lößlein L, Amend L, Frech M, Azizov V, Schälter F, Gessner A, Lucas S, Lesker TR, Taudte RV, Hofmann J, Beyer F, Bootz-Maoz H, Reich Y, Romano-Zadaka H, Mauro D*, Beckervordersandforth R, **Kragsnaes MS**, Ellingsen TE, Xiang W, Haghikia A, Akdis CA, Ciccia F*, Bäuerle T, Sarter K, Strowig T, Yissachar N, Schett G*, Rothhammer V, Zaiss MM*. **Gut-specific H3R signaling orchestrates microglia-dependent resolution of peripheral inflammation**. *J Clin Invest*. 2025 Jul 10:e184697. doi: 10.1172/JCI184697. *Citations: 1*

5. Hovmand KA, Z Acar Z, Jochumsen EA, Malig S, Kjeldsen J, Holm DK, Nilsson AC, Ellingsen T, **Kragsnaes MS**, Justesen US. **Culture Performance of the Fastidious Anaerobe Agar for Frequent Anaerobic Bacteria and Potential Application in EUCAST Antimicrobial Susceptibility Testing.** *Anaerobe* 2025 Jun;93:102972. doi: 10.1016/j.anaerobe.2025.102972. Epub 2025 May 19. PMID: 40398807. *Citations: 1*

6. Thorndal C, **Kragsnaes MS,** Nilsson AC, Holm DK, dePont Christensen R, Ellingsen T, Kjeldsen J, Bjørsum-Meyer T. **Safety and efficacy of faecal microbiota transplantation in patients with acute uncomplicated diverticulitis:** study protocol for a randomised placebo-controlled trial. *Therap Adv Gastroenterol* 2025 Jan 2;18:17562848241309868.

7. Jochumsen EA, **Kragsnaes MS**, Nilsson AC, Rasmussen KF, Ellingsen T, Juul MA, Kjeldsen J, Holm DK. 2024. **"Does This Fecal Microbiota Transplant Work?" Quality assurance of capsule based Fecal Microbiota Transplant production.** *Scand J Gastroenterol*. 2024 Nov;59(11):1234-1239. *Citations: 4*

8. Kragsnaes MS, Risbo N, Pedersen JK, Obel N, Finckh A*, Pedersen AB, Ellingsen T. **Antibiotics in inflammatory arthritis and background population one year before and after diagnosis: a nationwide drug utilisation study**. *Rheumatology* 2024 Aug 27:keae396. *Citations: 1*

9. Kragsnaes MS, Jensen JRB, Nilsson AC, Malik MI, Munk HL, Pedersen JK, Horn HC, Kruhøffer M, Kristinsen K, Mullish BH, Marchesi JR*, Kjeldsen J, Röttger R, Ellingsen T. **Dynamics of inflammation-associated plasma proteins following faecal microbiota transplantation in patients with psoriatic arthritis and healthy controls**. *RMD Open* 2024;10:e003750. *Citations: 10*

10. Kragsnaes MS, Blanco JM, Mullish BH*, Contreras-Serrano JI, Kjeldsen J, Horn HC, Pedersen JK, Munk HL, Nilsson AC, Salam A, Lewis MR, Chekmeneva E, Kristiansen K, Marchesi JR, Ellingsen T. **Small intestinal permeability and metabolomic profiles in feces and plasma associate with clinical response in patients with active psoriatic arthritis participating in a fecal microbiota transplantation trial**. *ACR Open Rheumatol* 2023;10.1002/acr2.11604. *Citations: 8*

11. Kragsnaes MS, Kjeldsen J, Horn HC, Munk HL, Pedersen JK, Just SA, Ahlquist P, Pedersen FM, de Wit M, Möller S, Andersen V, Kristiansen K, Holt HM, Holm DK, Christensen R, Ellingsen T. **Safety and efficacy of faecal microbiota transplantation for active peripheral psoriatic arthritis: an exploratory randomised placebo-controlled trial**. *Ann Rheum Dis* 2021 2021 Sep;80(9):1158-1167. *Citations: 86*

12. Kragsnaes MS, Sødergren ST, Kjeldsen J, Horn HC, Munk HL, Pedersen JK, Klinkby CS, de Wit M, Ahlmark NG, Tjørnhøj-Thomsen T, Ellingsen T. **Experiences and perceptions of patients with psoriatic arthritis participating in a trial of faecal microbiota transplantation**. *BMJ Open* 2021;11(3):e039471. *Citations: 18*

13. Kragsnaes MS, Nilsson AC, Kjeldsen J, Holt HM, Rasmussen KF, Georgsen J, Ellingsen T, Holm DK. **How do I Establish a Stool Bank for Fecal Microbiota Transplantation within the Blood- and Tissue Transplant Service?** *Transfusion* 2020;60:1135-41. *Citations: 22*

14. Kragsnaes MS, Kjeldsen J, Horn HC, Munk HL, Pedersen FM, Holt HM, Pedersen JK, Holm DK, Glerup H, Andersen V, Fredberg U, Kristiansen K, Christensen R, Ellingsen T. **Efficacy and safety of faecal microbiota transplantation in patients with psoriatic arthritis: protocol for a 6-month, double-blind, randomised placebo-controlled trial.** *BMJ Open 2018;8:e019231. Citations: 56*

15. Kragsnaes MS, Fredberg U, Stribolt K, Kjaer SG, Bendix K, Ellingsen T. **Stereological Quantification of Immune-competent Cells in Baseline Biopsy Specimens from Achilles tendons**: Results from Patients with Chronic Tendinopathy Followed for more than 4 Years. *Am J Sports Med*. 2014;42:2435-2445. *Citations: 65*

CORRESPONDANCES

1. Kragsnaes MS, Qin P, Kjeldsen J, Kristiansen K, Ellingsen T. **Response to: "Gut Microbiota Typing and Donor Factors Shape Fecal Microbiota Transplantation Response in Psoriatic Arthritis"**. Accepted for publication in *Arthritis Rheumatol.* Sept 2, 2025. DOI:10.1002/art.43394.

2. Kragsnaes MS, Kjeldsen J, Horn HC, Munk HL, Pedersen JK, Just SA, Ahlquist P, Davidsen JR, Nilsson AC, Röttger R, Kruhøffer M, Marchesi JR, Kristiansen K , Christensen R, Ellingsen T. 2023. **Response to Correspondence to 'Safety and efficacy of faecal microbiota transplantation for active peripheral psoriatic arthritis**: an exploratory randomised placebo-controlled trial'. *Ann Rheum Dis* 2023 Jul;82(7):e165.