FVC >10% from baseline to 2nd visit. For predicting models, predictors with $p < 0.2$ in the univariate analysis were included in the logistic regression analysis.

Results: 8013 LcSSc were included with a mean follow-up of about 3.3 ± 3.7 years. At baseline, mean $\pm$ SD mRSS was 6 ± 5 and ILD was present in 28.4% of all patients.

Worsening of skin fibrosis was observed in 6.4% (19/298), 7.8% (97/1248) and 9.8% (289/2957) of LcSSc patients at 6, 12 and 24 months follow-up respectively. In multivariate analysis, variables predicting skin fibrosis progression were elevated European Scleroderma Study Group activity index (EScSG-AI) (OR [95 IC]: 1.22 [1.05–1.4], $p = 0.007$) for 12 months progression and EScSG-AI (1.24 [1.13–1.38], $p < 0.001$) and mRSS (0.95 [0.93–0.98], $p = 0.001$) for 24 months progression.

Worsening of ILD was observed in 11.7% (23/196) and 19.9% (65/326) of LcSSc patients with ILD at baseline, at 12 and 24 months follow-up respectively. In multivariate analysis, variables predicting ILD progression at 24 months were EScSG-AI >3 (OR [95 IC]: 3.8 [1.51–9.56], $p = 0.005$), FVC (1.03 [1.01–1.04], $p < 0.001$) and LVEF (0.91 [0.85–0.97], $p = 0.005$).

Conclusions: It appears that only few LcSSc patients progress for skin fibrosis; this limits the use of mRSS in this subset and the potential of anti-fibrotic drugs of skin disease. However, a substantial rate of ILD progression was identified as well as relevant predictors. These results support the inclusion of LcSSc patients in SSc-ILD trials evaluating anti-fibrotic drugs. Our predictive models will be helpful to define enriched population in future clinical trials.

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OP0208

A PROOF-OF-CONCEPT DOUBLE-BLIND RANDOMISED PLACEBO-CONTROLLED TRIAL OF PROBIOTICS IN SYSTEMIC SCLEROSIS ASSOCIATED GASTROINTESTINAL DISEASE

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Background: Hypothesis: Gastrointestinal (GI) microbiota is a co-founding factor contributing to systemic sclerosis (SSc) and GI manifestations. Probiotics reduced GI symptoms by modulating microbiome composition in an open-label study.¹

Objectives: To determine whether probiotics result in reduction of GI symptoms in SSc patients, assessed using the UCLA Gastrointestinal Tract questionnaire (GIT 2.0).

Methods: In this double-blind placebo-controlled trial, 40 subjects with SSc (total GIT0.1) were randomised to receive 60 days of probiotics (900 billion units/day, composite of lactobacilli, bifidobacteria and streptococcus) or placebo, followed by 60 days of probiotics in both groups. Subjects on probiotics or antibiotics 30 days prior were excluded. Enrolled subjects were required to have stable doses of prednisolone, immunosuppression and GI medications 30 days prior and during the trial. Between group differences in total GIT change was assessed after 60 days (primary endpoint) and 120 days (secondary endpoint). Stool microbiome composition was analysed using 16S next generation sequencing. We performed principle coordinate analysis, alpha diversity and taxonomic level analyses. Two-sample t-tests were used to evaluate between-group differences, reported as mean $\pm$ SD. An intention-to-treat and last observer carried forward analysis was done. P -value < 0.05 was considered statistically significant.

Results: 40 subjects were randomised to placebo ($n = 21$) or probiotics ($n = 19$). Baseline characteristics are summarised in table 1. At the primary endpoint, change in total GIT was not statistically significant between placebo (-0.14 ± 0.27) and probiotic groups (-0.13 ± 0.31 ; $p = 0.85$). At the secondary endpoint, there was greater reduction in total GIT in the probiotic ($n = 13$; -0.18 ± 0.26) than the initial placebo group ($n = 15$; -0.05 ± 0.22), though not reaching statistical significance ($p = 0.14$). There was a statistically significant reduction in GIT-reflux subdomain in the probiotic group (-0.22 ± 0.16 vs initial placebo group 0.05 ± 0.27 ; $p = 0.0037$). Subjects on probiotics had greater abundance of lactobacillus, bifidobacterium and streptococcus, and exhibited high alpha diversity, whereas those on placebo had a decreasing trend of alpha diversity. Majority of adverse events were grades I and II.

Abstract OP0208 – Table 1 Baseline characteristics of subjects

	Probiotic (n=19)	Placebo (n=21)
Fulfil EULAR/ACR 2013 criteria, n (%)	19 (100)	21 (100)
Mean $\pm$ SD Age, years	51.4 (13.7)	50.7 (7.9)
Females, n (%)	19 (100)	16 (76.2)
Disease duration from non-Raynaud's onset, years	44.5 (14.2)	41.3 (9.7)
Diffuse subtype, n (%)	3 (15.8)	6 (28.6)
Anti-Centromere positive, n (%)	7 (36.8)	2 (9.5)
Anti-Topo-I positive, n (%)	2 (10.5)	10 (47.6)
Mean $\pm$ SD total GIT	0.42 (0.29)	0.41 (0.27)
Mean $\pm$ SD GIT Reflux	0.45 (0.44)	0.39 (0.39)
Mean $\pm$ SD GIT Distension	1.13 (0.70)	0.93 (0.74)
Mean $\pm$ SD GIT Diarrhoea	0.26 (0.44)	0.36 (0.60)
Mean $\pm$ SD GIT Fecal soilage	0.26 (0.71)	0 (0)
Mean $\pm$ SD Body Mass Index	23.6 (2.8)	22.9 (3.0)
Hydrogen breath test positive, n (%)	2 (10.5)	3 (14.3)
Prednisolone, n (%)	6 (31.6)	8 (38.1)
GI medications	13 (68.4)	18 (85.7)
GI: Proton-pump inhibitor	11 (57.9)	17 (81.0)
GI: Pro-motility agent	7 (36.8)	7 (33.3)
Immunosuppressive medications	10 (52.6)	13 (61.9)

Conclusions: This trial demonstrated safety of probiotics in SSc. The primary outcome at 60 days was not achieved. A prolonged course of probiotics (120 days) resulted in greater improvement of GI reflux. There was a possible positive association between reduced GI stress (evidenced by greater alpha diversity of the GI microbiota) and lower GIT scores in the probiotic group. This study provides justification for a larger definitive trial of probiotics in SSc.

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THURSDAY, 14 JUNE 2018

Patient involvement in research: The future of collaborative research. Lessons from the field of rheumatology and beyond

OP0209-PARE THE PATIENT VOICE IN ARTHRITIS RESEARCH: A COLLABORATIVE APPROACH TO EMBEDDING PPI INTO RESEARCH STRATEGY

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Background: Public and Patient Involvement (PPI) encompasses a variety of ways researchers engage with people for whom their research holds relevance. Active and formal PPI can result in increased patient support for research and improved likelihood of patient involvement in the case of clinical research, including improved relevance to patient quality of life. As a research centre, we decided to develop our own PPI initiative. In order to develop a meaningful and productive partnership, we have developed this initiative from conception with our patient insight partners.

Objectives: The overall objective is to improve our research quality, relevance and outcomes. We aim to ensure that the real-life experiences of people living with arthritis are considered in the decision making processes around arthritis research.

Methods: A community approach to recruitment of patient insight partners was used. Social media, advocacy charities, and local community events were the predominant source of recruitment. Three initiatives were proposed: steering committee, patient insight panels, and a patient educator programme. A discussion forum between patients and researchers was used to determine the feasibility, interest and accessibility of proposed initiatives. An independent facilitator was commissioned to prepare an unbiased report of the discussion forum, upon which the PPI strategy was developed.

Results: Patient support for the PPI initiative was overwhelmingly positive. A number of potential barriers to participation were identified.

1) Steering committee:

Risk of tokenism and the potential intimidation of a structure that was too formal. Mechanisms to overcome included multiple patient representatives, detailed terms of reference and a supportive environment with a rotating chair. Our patient insight partners proposed a three-tier structure: a patient focus group that