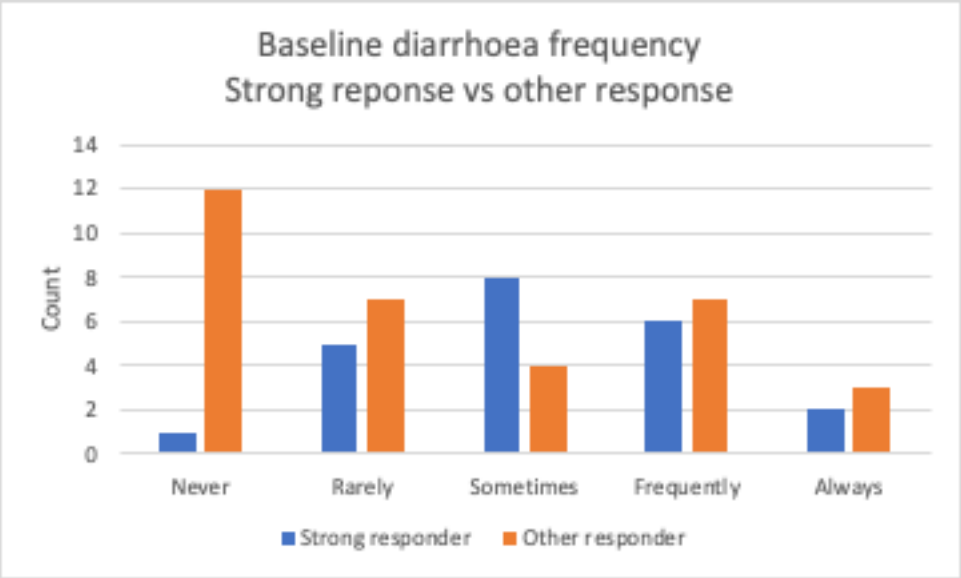
Notification of results of UCL autism probiotic study

Analysis of the study data for all the participants has shown no statistically significant differences on the primary or secondary outcomes when comparing Vivomixx to placebo. This means that in autistic children aged 3 to 16, with at least one gastrointestinal symptom (constipation, diarrhoea, abnormal stools, very odorous stools, abdominal pain, gaseousness or bloating, pain on defecation, reflux) persisting for six months, Vivomixx did not significantly reduce the frequency of gastrointestinal symptoms or improve global functioning when compared to placebo. There did appear to be some children who benefited from the treatment, but the averaged data for the whole group did not show any difference.
This study indicated that the safety of Vivomixx is good in this patient group with no serious adverse events reported and a slightly lower chance of any adverse event with Vivomixx compared to with placebo.

Although the enrolment had to halted in March 2020 due to Covid-19 lockdown, 69 participants were enrolled 69 into this crossover study (equivalent to 138 in a 1:1 parallel study) making it the largest autism probiotic study according to the most recent systematic review[1]. None of the outcome measures were approaching significance so it was not felt that the study was under-powered.
The primary outcome measure was the Autism Treatment Evaluation Checklist which encompasses measures of speech and language, sociability and awareness as well as physical health and behaviour. This measure was chosen as parents were interested in the wider possible effects of a probiotic rather than simply the effect on gastrointestinal symptoms. It is also a measure that has been shown to be sensitive to change, so it was not felt that the results reflected an incorrect selection of outcome measure.

There was a sub-group of participants that had a strong response to Vivomixx. Within this subgroup there appears to be a significant relationship between the frequency of diarrhoea at the start of the study and having a strong positive response to Vivomixx. From the study data, those children who had not suffered any diarrhoea in the 2 months prior to starting the study, were much less likely to have a strong response to Vivomixx. Also those children who had sometimes suffered diarrhoea in the 2 months prior to starting the study, were much more likely to have a strong response to Vivomixx. This is illustrated in the chart below;



1. Tan, Q.; Orsso, C.E.; Deehan, E.C.; Kung, J.Y.; Tun, H.M.; Wine, E.; Madsen, K.L.; Zwaigenbaum, L.; Haqq, A.M. Probiotics, prebiotics, synbiotics, and fecal microbiota transplantation in the treatment of behavioral symptoms of autism spectrum disorder: A systematic review. *Autism Res.* **2021**, *14*, 1820–1836.