

"ME/CFS in the UK and Norway: comparing RESTORE-ME and the COMEBACK Study"

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A little over a year ago I wrote <u>a blog post</u> about my PhD project and the RESTORE-ME clinical trial, and it is time for an update.

For those who do not remember, my project is funded by Invest in ME Research and the University of East Anglia.

It focuses on the role of human viruses in ME/CFS.

Specifically, we are interested in which viruses are present in the gut of people with ME/CFS, and how these viruses relate to the severity of symptoms. Viral infections are often associated with ME/CFS. Many people with ME/CFS also have intestinal



disturbances like irritable bowel syndrome, and an imbalance of the gut microbiota composition.

And, since the gut and its microbes play an important role in our immune system, we want to find out if there is a link between these gut microbes and viruses.

The RESTORE-ME trial will give some insight, by attempting to replace the existing microbiota with those from a healthy donor, using a treatment called faecal microbiota transplantation (FMT).

From this trial, we will learn whether microbiota replacement can help alleviate ME/CFS symptoms. And by analysing the gut viruses, we can find out if there are any viruses that are associated with ME/CFS symptomatology.

Unfortunately, the trial has had some delays. There have been changes in MHRA regulations, which required modifications to our facility, and the trial is now expected to commence in the third quarter of this year.

Rik Haagmans

Last year in Harstad, in the north of Norway, researchers started a similar trial. It is called the Comeback Study, and is led by Linn Skjevling and Dr. Peter Johnsen.

Both studies enrol people with ME/CFS and IBS and take the first measurement after 3 months.

One difference between the studies is that the Comeback study recruits residents of Norway, while UK residents will be enrolled in the RESTORE-ME trial.

That might not seem very significant at first glance. But there are lots of differences between people living in different countries, which affect the composition of your gut microbes.

For example in lifestyle, environment, and diet.

On top of that, our studies use different methods of delivery (colonoscopy or capsules vs. retention enema), final measurement time point (6 months vs. 12 months), and outcome measures (accelerometer and cognitive test results vs. fatigue scale).

So, these studies will complement each other nicely, and comparing the results of both trials might offer new insights into differences between ME/CFS in our countries.

It will also provide information on methods to and help inform further studies of FMT in people with ME/CFS.



Our research groups have now joined forces in various analyses. I will travel to Harstad and Tromsø, to help processing samples and prepare extracts for virome analysis. **Rik Haagmans**

We will ship those extracts to Norwich, where they will be processed and analysed further.

We can then determine which viruses live in the gut of people with ME/CFS and see if any changes in the presence of these viruses after FMT is associated with successful treatment.

The same samples will also be analysed in Norway, to determine changes in the microbiome composition. Together, this will give us a lot of information on what's going on with the gut microbes and viruses, how FMT affects them, and how this relates to ME/CFS.

I am very excited about this project, not the least because Norway is a beautiful place to visit, and I will be going at a nice time of the year.

But most importantly, it will provide additional data on ME/CFS and FMT. I also think this collaboration will be a good development.

It will be good for both our groups, as we will learn from each other's research. And it will be good for ME/CFS research, as international collaborations like this can help develop research standards that improve research quality and consistency.

Rik Haagmans - Quadram Institute, Norwich

Further Reading:

- <u>RESTORE-ME: Restoring gut microbiota to treat Myalgic</u> <u>Encephalomyelitis/Chronic Fatigue Syndrome</u>
- <u>RESEARCH NEWS: New Award for Research into ME in Norwich Research</u>
 <u>Park</u>
- Project Description
- Invest in ME Research funded projects
- Quadram Institute Research into ME
- <u>The Carding Lab Quadram Institute</u>
- European Infrastructure Development