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Personalised Nutrition in Non-Alcoholic Fatty Liver Disease (NAFLD): Feasibility of a Nutrigenomic Therapeutic Approach
Clinical Study Results

This is a summary of the main results from a study titled: Personalised Nutrition in Non-Alcoholic Fatty Liver Disease (NAFLD): Feasibility of a Nutrigenomic Therapeutic Approach. Trial registration number ISRCTN93410321.

This research was funded by the National Institute for Health and Care Research (NIHR) Newcastle Biomedical Research Centre (BRC) (grant number BRC-1215–20001) as part of an educational qualification (PhD). The design and organisation of the study was the responsibility of Laura Haigh and Professor Quentin Anstee who are recognised as experts in this field.

Thank you!

We thank all the participants of this study. We hope this summary helps the participants understand the important role and contribution they made in this research.

What was the purpose of the research?

NAFLD affects 1 in 3 people and ranges from simple fatty liver through steatohepatitis (liver fat and inflammation) to cirrhosis (liver fat, inflammation, and cell damage). NAFLD is more likely to develop in people who are overweight or have Type 2 diabetes. People with NAFLD that carry a gene called *PNPLA3* are more likely to develop advanced liver disease.

Currently, the main treatment is to lose weight and eat a healthy diet. The Mediterranean diet is a model of healthy eating that is often recommended for people with NAFLD. More research is needed on how it works in the liver to bring about its benefits. We also need to understand how the *PNPLA3* gene affects an individual's response to different types of diet treatments.

The purpose of the current study was to develop and test different methods for a future randomised controlled trial that will investigate if the *PNPLA3* gene influences response to a Mediterranean diet in people with NAFLD. The current study took place between 13th January 2020 to 30th September 2021 in outpatient liver services at The Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH).

What happened during the study?

Participants with NAFLD attended a small number of visits to the liver outpatient department at NuTH. They received one-to-one dietary advice from a dietitian. This advice involved following a Mediterranean diet for one month and an alternative diet (regular diet) for one month, with up to three months between the two on their regular diet. Some Mediterranean diet foods were supplied free of charge, such as pre-packaged ready meals (FreshPrepare)

and extra virgin olive oil 750ml (Filippo Berio). Participants were asked to maintain their current level of physical activity and weight throughout the study.

The researchers captured information on how easy it was to follow the diets and to complete the main tests. Cutting-edge indicators (biomarkers) from urine and blood were tested to understand how well people followed the diets and provide early data on whether people with the *PNPLA3* gene respond differently to the diets.

What were the results of the study?
All the participants helped the researchers learn more about the feasibility and acceptability of different methods for a future randomised controlled trial. The researchers found that conducting a larger study in the future is possible by adjusting the diets, instruments, and main tests. In this future study, the researchers might explore how cost-effective it is, involve patients and the public more extensively, and create an interactive web-based platform to help people make dietary changes.

Although the research's focus was not to examine the effects of the diets. They observed that the study helped people more closely follow the Mediterranean diet over four weeks. These dietary changes could potentially lead to positive benefits for heart and liver health.

How has this study helped patients and researchers?
The study's results have helped the researchers learn important information about how to design the future study and improve the diets. The findings have provided early indication of the potential benefits of a Mediterranean diet, in regions where people typically follow a western diet. These findings might help guide the development of a larger-scale study.

The results of this study are based only on the participants included in this study. This summary shows only the main results from this one study. Other studies may provide new information or different results.

This summary is for informational purposes only. If you need medical advice about your own health or situation, please contact your doctor. Further studies are planned to build upon these findings.

Where can I learn more about this study?
You can find more information about this study at the website listed below:

ISRCTN registry

The results of the study may be published in a relevant liver/nutrition journal(s). The participants will not be identified in any report or publication. The participants are welcome to have a copy of the results once they are published.

Who sponsored and reviewed this study?
Ethical approval was granted by East of Scotland Research Ethics Service REC 1 (19/ES/0112). NHS Research and Development approval was granted by The Newcastle upon Tyne Hospitals NHS Foundation Trust (R&D8985).