Participant Information Sheet

Research study: Assessing the feasibility of an evidence-informed digital intervention to support self-management in people with non-alcoholic fatty liver disease

You are being invited to take part in this research study. Before you decide, it is important for you to read this leaflet so you understand why the study is being carried out and what it will involve.

Reading this leaflet, discussing it with others or asking any questions you might have will help you decide whether or not you would like to take part.

What is the purpose of the study?

Non-alcoholic fatty liver disease (NAFLD) affects up to 1-in-3 adults in the UK and is closely linked with overweight or obesity. Currently, there are no licenced drug treatments for NAFLD. The main treatment is lifestyle change with weight loss being central to improving liver health. Despite the positive effect of lifestyle change on liver health, structured lifestyle programmes for are *not* routinely used/available in clinical care.

We have developed an evidence-based digital intervention targeting lifestyle change for patients with NAFLD **(VITALISE- interVention to promote lIfesTyle change in non-Alcoholic fatty LIver diseaSE).** The in-depth developmental process involved significant patient input and received positive feedback via usability testing. However, VITALISE has not yet been used/tested as part of routine clinical care.

Our study aims to assess the feasibility of using VITALISE in the clinical setting. Patients recruited to the study will have access to VITALISE for 6-months and will be supported by tele-coaches to set personalised goals linked to weight loss, dietary change and physical activity. We will collect data on whether patients find VITALISE acceptable: can/do they use it?; how we can improve usability; and how we can improve uptake. We will also collect preliminary data on clinical outcome measures collected as part of routine care.

This will be the first study to provide evidence for the feasibility of using VITALISE in routine clinical care for patients with NAFLD. We will use this data to inform a future funding application to allow a larger scale evaluation of VITALISE in the NHS.

Why have I been invited?

We are looking to recruit men and women over the age of 18 years, who have been recently diagnosed with NAFLD. You have been invited to this study because you are one of these patients.

What will happen if I take part?

Everyone who agrees to take part will be given a personal login for the VITALISE programme which you will have continuous access to for 6-months over the internet. You will be supported by trained coaches who will offer monthly personalised coaching sessions over the phone.

VITALISE has been developed in collaboration with a local telehealth company called 'Changing Health'. Changing Health currently provide digital interventions for people with Type 2 Diabetes across the UK and are an accredited company within the NHS. We will ask your permission to provide Changing Health with your full name and email address – Changing Health will then send you a welcome email allowing you to access the VITALISE programme.

You will **NOT** be asked to attend any additional visits to the hospital outside of your normal clinic visits. However, we will collect some additional information about you at your normal clinic visits (see study visits below).

Overview of VITALISE content:

Module	Content
Module 1: Introduction	Welcome to the programme
Module 2: Understanding non-alcoholic fatty liver disease (NAFLD)	What is NAFLD?
	How is NAFLD identified and diagnosed?
	Understanding test results
	NAFLD myths
	Managing your NAFLD
	Patient success stories
	Long term complications of NAFLD
Module 3: Getting started with coaching	
Module 4: Food and NAFLD	Energy balance
	Nutrition and NAFLD
	Understanding carbohydrates
	Understanding fats
	Understanding alcohol
Module 5: How do I make changes to my diet?	Finding the right dietary approach
	Calorie restriction
	Mediterranean diet
	Alternative dietary approaches
Module 6: Practical tips	Supermarket tour
	Food labels
	Portion sizes
	Healthy eating
Module 7: Physical activity, exercise and NAFLD	How lifestyle can contribute to weight gain and NAFLD
	Combining physical activity and diet to promote weight loss
	Physical activity, exercise and NAFLD
	How much physical activity do I need to do?
Module 8: Steps to Success	5 essential steps to goal setting
	Behavioural goal setting

	Dietary goal setting
	Step tracker
	Weight tracking
	Maximising chances of success

Study visits

You will **NOT** be required to make any separate visits to the hospital as part of this study. It is our intention that all study measures will be undertaken at your normal outpatient clinic visits**.**

The measures detailed below will be undertaken when you enroll in the study (at baseline) and approximately 6-months later, when you have completed the VITALISE programme.

You will be asked to complete a medical questionnaire requesting some personal information and details of your medical history and current medications. We will measure your resting blood pressure, weight, height, and waist and hip circumference. You will also undergo a fibroscan to measure your liver stiffness. **All of these measures will be taken as part of your normal clinical care.** The researcher will then ask you to complete two short questionnaires: the Patient Activation Measure (PAM) which asks how confident you are in managing your NAFLD and a physical activity questionnaire. You will complete the questionnaires yourself, but the researcher will be there to answer any questions. You will also be given an activity monitor to wear for 7-days before you start the programme and after you finish. This will be returned to the research team in the post in a pre-paid envelope.

The researcher will send your full name and email address to Changing Health who will send you a welcome email allowing you to access the VITALISE programme. The researcher will familiarise you with how to access the programme on the internet and how to book appointments with the tele-coaches. You will receive a pedometer to measure your daily step count which can then be added to your VITALISE profile.

A member of the research team will telephone you after 12 weeks to answer any questions and to record your weight, physical activity levels (step count and questionnaire) and complete the PAM.

After you have completed the VITALISE programme, we will ask if you would be willing to undertake a short interview on the telephone with a member of the research team. The interview will focus on your expectations, benefits, motives and barriers to taking part in the programme. The interview will last approximately 30 minutes and will be audio-recorded. Audio recordings will be transcribed by a transcription company and deleted upon transcription**.** A confidentiality agreement will be in place to cover this work. If quotes from the interviews are used, they will be anonymised.

No additional biological samples will be collected as part of this study. We will only be using the results from your blood tests taken as part of your standard clinical care.

After the study finishes, you will still be able to login to the VITALISE programme but will no longer be able to access coaching appointments.

Do I have to take part?

No. It is up to you whether you would like to join the study. We are giving you this information sheet to help you decide whether you want to take part or not. If you do decide to take part, remember that you can stop being involved in the study whenever you choose, without telling us why. Deciding not to take part, or leaving the study, will not affect your usual care or treatment plan in any way.

What are the possible benefits of taking part?

There are many potential benefits to accessing the VITALISE programme. This includes access to credible, up-to-date information on what NAFLD is and how to manage it through lifestyle change. The information included in the programme is based on clinical guidelines and the tele-coaches have been trained specifically to support people with NAFLD to make informed, personalised changes to their daily lives to improve their liver health. We hope that the programme will help people with NAFLD to lose weight and become more physically active.

What are the possible disadvantages of taking part?

We will schedule your assessments on the same day as your routine visit to the hospital, however, this will extend the length of your appointment by up to 30 minutes.

Accessing the VITALISE programme will take up some of your time but it will be up to you when you choose to access it and you can arrange the coaching appointments at a time that suits you.

Will my taking part in this study be kept confidential and anonymous?

We will send a letter to your GP to let them know that you are taking part in this study.

We will not write your name on any of the data we collect. We will replace your name with a unique ID number, which means your data will not be personally identifiable. This is known as ‘pseudonymisation’. The consent form you have signed will be stored separately from your other data. None of your personal information will be discussed with anyone outside of the direct research team.

All paper records and electronic data will be stored securely and kept confidential. Your privacy is extremely important to us and every effort will be made to ensure your involvement and personal information remains secure. The only exception to this confidentiality is if the researcher feels that you or others may be harmed if information is not shared.

We will provide Changing Health with your full name and email address so that they can send you a welcome email allowing you to access the VITALISE programme. You will be able to track your weight, diet and physical activity levels (steps) within VITALISE but it will be up to you what data you enter. The coaches will use the data you submit within your profile to tailor the tele-coaching sessions to meet your personal needs.

How will we use information about you?

We will need to use information from you and your medical records for this research project.

This information will include your name, contact details, age, ethnicity, medical history, relevant clinical tests, dietary habits, and level of physical activity. We will also collect some health-related data from you such as your blood pressure, weight and height. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

Where can you find out more about how your information is used?

You can find out more about how we use your information;

at www.hra.nhs.uk/information-about-patients/
our leaflet available from www.hra.nhs.uk/patientdataandresearch
by asking one of the research team
by sending an email to the Data Protection Officer contact at NuTH: nuth.dpo@nhs.net

What will happen to the results of the study and could personal data collected be used in future research?

The general findings might be reported in a scientific journal or presented at a research conference. Results will also be made available via our LiverNorth patient support group and the Newcastle upon Tyne NHS Hospitals Charity in their newsletters, however the data will be anonymised and you or your data will not be personally identifiable. Please feel free to email

the researcher at the address below if you would like us to provide you with a summary of the study findings.

Data that we have collected during this research could be used in future research. This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

Who is organising and funding the study?

The Newcastle upon Tyne Hospitals NHS Foundation Trust (The Sponsor) and Newcastle University are jointly organising this study (R & D ref: 10121). The sponsor has insurance policies in place to cover the research. Funding for the study has been awarded by the Newcastle upon Tyne NHS Hospitals Charity.

Who has reviewed this study?

The North East-Tyne & Wear South Research Ethics Committee have reviewed the study to safeguard your interests and have granted approval to conduct the study.

What if something goes wrong?

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against The Newcastle upon Tyne Hospitals NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Contact for further information:

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