

VITALISE - intervention to promote lifestyle change in non-alcoholic fatty liver disease

Submission date 02/08/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 30/08/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/07/2025	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

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 a 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.

Who can participate?

Adults with NAFLD

What does the study involve?

We have developed an evidence-based intervention targeting lifestyle change for patients with NAFLD (VITALISE- interVention to promote lIfeStyle change in non-Alcoholic fatty LIver diseaSE). The 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/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 inclusivity. 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.

What are the possible benefits and risks of participating?

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. The possible risks will include assessments on the same day as your routine visit to the hospital as 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.

Where is the study run from?

Freeman Hospital, The Newcastle upon Tyne Hospitals NHS Foundation Trust (United Kingdom)

When is the study starting and how long is it expected to run for?

January 2022 to March 2024

Who is funding the study?

Newcastle upon Tyne Hospitals NHS Charity (United Kingdom)

Who is the main contact?

Dr Kate Hallsworth (United Kingdom)

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Contact information

Type(s)

Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

313662

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS 313662, CPMS 52889

Study information

Scientific Title

Assessing the feasibility of an evidence-informed digital intervention to support self-management in people with non-alcoholic fatty liver disease (VITALISE- interVention to promote lIfesTyle change in non-Alcoholic fatty LIver diseaSE)

Acronym

VITALISE

Study objectives

The aim of the proposed study is to evaluate the feasibility and acceptability of VITALISE in the clinical setting. This feasibility trial will not include formal hypothesis testing because it is not powered to detect clinically meaningful changes in outcomes. The main aim of the feasibility study is to gain insight into whether patients find VITALISE acceptable: can/do they use it?; how can usability be improved?; how can inclusivity be improved? And whether it is feasible to deliver the intervention within routine clinical care.

In line with NIHR and CONSORT guidance for feasibility studies, the primary objectives are to determine recruitment, retention and attrition rates, intervention uptake, engagement, adherence, and follow-up rates and to test the robustness of our data collection procedures. We will collect data on usability and individual patient views on VITALISE via semi-structured interviews. Importantly, we will look at the demographics of patients who participate versus those who decline. We will seek information from those who decline to explore ways in which these barriers can be overcome.

The secondary objective is to determine whether acceptability and feasibility lead to changes in outcomes including body weight, HbA1c, liver enzymes, liver stiffness, blood pressure and lipid profile (all measured as part of standard care using the NuTH NAFLD Care Bundle). These preliminary data will provide some indication of whether the intervention could be effective as part of routine clinical care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 30/05/2022, North East - Tyne & Wear South Research Ethics Committee (Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 (0) 2071048306; tyneandwearsouth.rec@hra.nhs.uk), ref: 22/NE/0090

Study design

Single-centre one-arm prospective-design feasibility study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Home

Study type(s)

Treatment

Participant information sheet

See study outputs table

Health condition(s) or problem(s) studied

Non-alcoholic fatty liver disease (NAFLD)

Interventions

Patients will be given a personal login for the VITALISE programme and will have continuous access for a 6-month time period prior to their follow-up appointment with a hepatologist. Patients will be supported by monthly personalised coaching sessions delivered by specifically trained tele-coaches. Patients will be provided with a pedometer to allow them to record their daily step count.

Intervention Type

Behavioural

Primary outcome measure

Criteria used to judge the feasibility of progressing to a larger scale evaluation:

1. Total number of patients recruited per month measured using data from a screening log over 6 months
2. Percentage of recruited patients who log in measured using data from the VITALISE digital platform during their 6-month intervention
3. Percentage of patients who logged in to VITALISE and provide follow-up data logged during the follow-up visit at 6 months

These criteria aim to retain a sufficient sample size to determine acceptability and feasibility.

Secondary outcome measures

To determine whether acceptability and feasibility lead to changes in clinical outcomes, including:

1. Body weight
2. HbA1C
3. Liver enzymes
4. Liver stiffness
5. Blood pressure
6. Lipid profile

All measured as part of standard care using standard methods at baseline and 6 months

Overall study start date

11/01/2022

Completion date

31/03/2024

Eligibility

Key inclusion criteria

1. Aged 18 years and over
2. Clinical diagnosis of NAFLD following review by a hepatologist within the last 6 months
3. Willing and able to give written informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

35

Total final enrolment

35

Key exclusion criteria

1. Decompensated NASH cirrhosis (Child Pugh score ≥ 7)
2. Diagnosed/previous eating disorder or purging
3. Excessive alcohol consumption (>14 units/week for females; >21 units/week for males)
4. Known cancer (except skin cancer)
5. Myocardial infarction within 6 months or uncontrolled cardiovascular disease
6. Pregnant/considering pregnancy
7. Inability to understand written and verbal English

Date of first enrolment

01/11/2022

Date of final enrolment

31/05/2023

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital

Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation

Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details

Level 1 Regent Point
Regent Farm Road
Gosforth
Newcastle upon Tyne
England
United Kingdom
NE3 3HD
+44 (0)191 2825789
nuth.nuthsponsorship@nhs.net

Sponsor type

Hospital/treatment centre

Website

<http://www.newcastle-hospitals.org.uk/>

ROR

<https://ror.org/05p40t847>

Funder(s)

Funder type

Charity

Funder Name

Newcastle upon Tyne Hospitals NHS Charity

Results and Publications

Publication and dissemination plan

- 1. Planned publication in high-impact peer-reviewed journals
- 2. Presented at local, national and international meetings and conferences
- 3. Results of the study will also be made available via the LiverNorth patient support group and the Newcastle upon Tyne Hospitals NHS Charity through both oral presentations and in their newsletters

Intention to publish date

30/06/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository

IPD sharing plan summary

Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 4.0	08/06/2022	08/08/2022	No	Yes
Protocol article		19/04/2023	20/04/2023	Yes	No
HRA research summary			28/06/2023	No	No
Results article		30/06/2025	02/07/2025	Yes	No