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

Submission date
02/08/2022

Recruitment status
No longer recruiting

Registration date
30/08/2022

Overall study status
Completed

Last Edited
02/07/2025

Condition category
Digestive System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
313662

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

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

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Charity

Funder Name
Newcastle upon Tyne Hospitals NHS Charity

Results and Publications

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?
Results article		30/06/2025	02/07/2025	Yes	No
Protocol article		19/04/2023	20/04/2023	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version 4.0	08/06/2022	08/08/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes