ISRCTN62558470 https://doi.org/10.1186/ISRCTN62558470

Developing a tailored digital intervention to improve adherence to statin medications

Submission date
20/05/2024

Recruitment status
Recruiting

Registration date
31/05/2024

Overall study status
Ongoing

Last Edited
09/05/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Statins are a type of medication that helps to reduce the levels of "bad" cholesterol in the body, which in turn lowers the risk of heart attacks, strokes, and death. However, many patients do not take these medications as prescribed, making them less effective. Adherence to statins is lower compared to other long-term medications, with only 25% of patients continuing to take them as prescribed after 2 years. Within a year of being prescribed statins, 40-60% of patients stop taking them altogether.
The reasons for this are often factors that can be changed, such as worrying about side effects or forgetting to take the medication. Researchers have studied these factors, but more work is needed to understand why some groups, such as ethnic minorities and people from underprivileged backgrounds, have even lower adherence rates. Currently, there are no affordable interventions addressing patients' unique barriers and using psychological theory to improve statin adherence.
This study aims to create a new scalable intervention that is tailored to each individual and based on behavioural science frameworks to improve adherence to statins.

Who can participate?
Patients aged 18 years and over who are taking statins and healthcare workers from primary care

What does the study involve?
Patients will participate in a 45-minute interview online or in person, depending on their preference, to explore their barriers and facilitators to taking statins. The second part of the study will involve running six 2-hour workshops (in-person and online) with patients and healthcare workers to develop the intervention. Between workshops, stakeholders will assess if the intervention is feasible to implement in practice.
The intervention will then be user-tested with a small sample of participants for a short period of time. After trying the intervention, participants will complete a follow-up questionnaire on acceptability and intervention usage. They will also be invited to participate in a one-hour focus group to provide feedback on the intervention and co-design improvements.

What are the possible benefits and risks of participating?
Interviews, workshops and user testing might be time-consuming for participants. Therefore,

interviews will be scheduled at a time and place to suit the participant or will be online if preferred. Workshops will be online or in-person during the early evening or working hours. Workshops will also have breaks and will last a maximum of two hours. For user testing, the intervention will be delivered for a short period of time with a survey that could be completed directly on participants' phones. The focus group will be online or in-person, depending on the group's preference and will last an hour. There is no reasonable expectation that any harm will arise from these activities.

Where is the study run from?
1. Imperial College London (UK)
2. Hammersmith & Fulham (H&F) Partnership GP Practices (UK)

When is the study starting and how long is it expected to run for?
November 2023 to June 2026

Who is funding the study?
1. NIHR Research for Patient Benefit (RfPB) programme (UK)
2. London Interdisciplinary Social Science Doctoral Training Partnership (LISS DTP) (UK)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
324941

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
23SM8299, CPMS 58875, IRAS 324941

Study information

Scientific Title
Promoting STatin Adherence with a Tailored Intervention

Acronym
STATIN

Study objectives
This study aims to develop a scalable yet individually tailored intervention to improve adherence to statin medications using behavioural science frameworks. To achieve this aim, the following

objectives will be pursued:
1. To identify key modifiable statin adherence factors among different patient groups.
2. To co-design a theory-based, scalable, individually tailored intervention to support statin adherence.
3. To conduct user testing to optimise the intervention

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/11/2023, North East - York Research Ethics Committee (2 Redman Place, London, E20 1JQ, United Kingdom; +44 (0)207 104 8079; york.rec@hra.nhs.uk), ref: 23/NE/0192

Study design
In-depth interviews, co-design workshops with patients and healthcare workers and user testing of tailored statin adherence intervention

Primary study design
Observational

Secondary study design
Qualitative study

Study setting(s)
GP practice, University/medical school/dental school

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Dyslipidemias in patients taking statins

Interventions
The first part of the study will consist of 15-17 semi-structured interviews with patients. Under-researched populations will be targeted to identify key determinants across diverse groups of patients. Participants will be purposefully recruited to ensure representation from different adherence levels (low adherence, adherent, and never initiated) and demographics. A screening survey will be used to confirm diverse representation and guide targeted recruitment if needed. A topic guide based on the Theoretical Domains Framework (TDF) will guide the interviews. Inductive thematic analysis will be conducted and then identified themes will be mapped deductively onto the TDF domains. Results will be analysed iteratively, and more interviews will be conducted if saturation has not been reached within groups.

Following the interviews, three sets of two workshops (6 workshops in total), each lasting 2 hours and each with approximately 8-12 participants, will be conducted. Workshops will take place in multiple formats (in-person, online, various times) to promote inclusivity. Similar to the

interviews, participants will be purposefully recruited to ensure a diverse range of patients. The final set of workshops will include primary care staff to gain their input on intervention feasibility.

The intervention will be user experience tested and refined throughout the process. Ten participants will receive the intervention within a short time frame with flexible adaptation over time. Participants trying the intervention will answer a brief survey to assess intervention usage. They will also be invited to participate in a one-hour focus group to provide feedback on the intervention and co-design improvements. The discussion will explore acceptability, how easy the service was to use, and any other aspects (technological or otherwise) that decreased engagement.

Intervention Type
Other

Primary outcome measure
1. Modifiable factors (barriers and facilitators) affecting adherence to statin medications measured using interviews based on Theoretical Domains Framework
2. Acceptability of intervention measured by focus groups based on Theoretical Framework of Acceptability at user testing
3. Usability of intervention measured using the System Usability Scale (SUS) questionnaire at user testing
4. Intervention engagement measured using digital log files at user testing

Secondary outcome measures
1. Key statin adherence modifiable factors for different groups of patients measured by interviews
2. Self-reported statin adherence measured using the 3 item Likert scale from Voils 2012 at recruitment
3. Sociodemographic characteristics measured by pre-screening questionnaire at recruitment

Overall study start date
01/11/2023

Completion date
12/06/2026

Eligibility

Key inclusion criteria
Patients:
1. Have been prescribed statins
2. 18+ years old

Health professionals:
1. Clinical pharmacists, General Practitioners (GPs), practice nurses or healthcare assistants
2. Regularly prescribe statins, or consult with, or advise patients on their statin therapy

Participant type(s)
Patient, Health professional

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
89

Key exclusion criteria
Patients:
1. Age >18 years old
2. Pregnant women
3. Patients who have never been prescribed statins
4. Cognitive impairment
5. Severe life-limiting condition
6. Did not speak English if a translator cannot be arranged for them
7. Did not consent to participate

Health professionals
1. Working only on secondary care
2. Without experience in prescribing statins, managing, or advising patients on following statin therapy

Date of first enrolment
10/01/2024

Date of final enrolment
01/03/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial College London
Norfolk Place
London
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W2 1PG

Study participating centre
Richford Gate Medical Centre
Richford Gate
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Sponsor information

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Sponsor type
University/education

Website
https://www.imperial.ac.uk/research-and-innovation/research-office/research-governance-and-integrity/

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
London Interdisciplinary Social Science Doctoral Training Partnership (LISS-DTP)

Results and Publications

Publication and dissemination plan
Academic outputs published in open-access high-impact, peer-reviewed academic journals. The developed intervention will be shared with study participants, and everyone involved in co-design (email summary, and invitation to a demonstration meeting with a recording shared afterwards). Findings will be also presented at well-attended conferences, seminars and regular engagement activities for community groups, patients and carers.

Intention to publish date
01/06/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed in this study will be available upon request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 8	10/10/2024	15/11/2024	No	No
Protocol file	version 9	07/03/2025	09/05/2025	No	No