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Text messaging and training to support the taking of statins

Submission date
31/01/2022

Recruitment status
No longer recruiting

Registration date
01/02/2022

Overall study status
Completed

Last Edited
04/06/2024

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Background and study aims
Patients often do not take statins regularly when they are prescribed them, either because they forget, or because they believe they are unnecessary or will have unwanted side effects. Previous research has shown that text message reminders for medications may help patients to take them more regularly. Furthermore, healthcare staff sometimes do not prescribe the correct amount of statins to patients who need them, potentially because they think that stronger prescriptions are not necessary or they may cause side effects. This puts patients at risk. No research so far has provided patients prescribed statins with informational reminders in a simple and low-cost way, whilst also educating healthcare staff on the importance of prescribing the right amount of statins. In this study the researchers are planning to do this, their overall objective being to increase statin use.

Who can participate?
Practices with a list size of at least 6,000 patients within the participating regions, and their enrolled patients aged between 18 and 75 years with high blood cholesterol and at least one of the following conditions: type 2 diabetes; hypertension; chronic kidney disease or heart disease; who are receiving a prescription for any type of statin for at least the last 12 months

What does the study involve?
After recruiting the required number of practices the researchers will identify patients who are in need of support in taking their statins regularly. In half the practices they will then use the systems that are already in place in practices to send reminders for appointments in order to send text messages to these patients to remind them to take their statins regularly. These patients will receive these messages at a set frequency for 12 months, after which the researchers will measure if this has affected how regularly they collect their statins. Healthcare staff from these practices will also be invited to attend educational sessions designed to help them support their patients to take enough statins, and then measure if this has affected prescription and usage habits 12 months later. There will be no change to the prescribing procedures in the other practices. A comparison of the two groups of practices will show whether the combination of text message reminders and educational support for doctors has decreased the level of blood fats in these patients.

What are the possible benefits and risks of participating?
If successful, the combination of text message reminders and educational support will ensure that these patients will be supported to take the correct statin dosage more regularly, which will improve their health. Also, this study will provide a template for how similar programmes can be rolled out at other GP practices around the country.

Where is the study run from?
NIHR ARC East Midlands (UK)

When is the study starting and how long is it expected to run for?
July 2019 to December 2024

Who is funding the study?
NIHR ARC East Midlands (UK)

Who is the main contact?
Dr Patrick Highton
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Contact information

Type(s)
Scientific

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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
280020

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 51348, IRAS 280020

Study information

Scientific Title
Complex intervention comprising text MEssaging anD HEalthcare professionaL training for imProving statin adherence in primary care: a pragmatic cluster-randomised controlled trial (MED-HELP)

Acronym
MED-HELP

Study objectives
Training provided to clinicians with prescribing responsibilities combined with regular supportive reminder text messages delivered to patients who may be struggling to take their statins as prescribed will improve statin prescribing habits and increase statin prescription, resulting in improved low-density lipoprotein-C results in these patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/01/2022, Leicester Central REC (East Midlands, UK; +44 (0)207 104 8066, +44 (0) 2071048181; leicestercentral.rec@hra.nhs.uk), REC ref: 21/EM/0272

Study design

Randomized; Interventional; Design type: Prevention, Process of Care, Education or Self-Management, Complex Intervention

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hypercholesterolaemia

Interventions
This pragmatic study will employ an open-labelled, randomised controlled trial design, using cluster randomisation at the practice level. GP practices (representing clusters of individual patients) will be recruited from across several geographical regions (in collaboration with other NIHR ARC infrastructures). Practice staff will not be blinded to allocation. There will be 40 practices in total taking part in this study (20 randomised to control cluster, 20 randomised to intervention cluster).
Practices will be approached to take part and pre-screened for practice eligibility prior to agreements being signed and consent being taken. Following consent, the randomisation process will be carried out by an independent statistician from the University of Leicester to ensure allocation concealment from practices and from the study team staff. Otherwise, this will be an open, unblinded trial as study staff and practices will need to be made aware of their group allocation. However, in line with what happens in real practice settings, we consider there will be minimal contamination between practices. Cluster (GP practice) numbers will be assigned sequentially as each practice enters the study. The practices will be assigned to either the control or intervention arm on a 1:1 basis, stratified for ARC site, list size and ethnicity (White European or other ethnic minority including Black and Asian). The decision to stratify by ethnicity was based on previous experience with a similar study in which an unequal randomisation allocation of ethnic minority participants occurred. As this study will be run in the same location, which has a high ethnic minority population, stratification by ethnicity is considered to be necessary. An electronic software application (facilitated by PRIMIS at the University of Nottingham) will be used to identify and flag patients that fulfil the inclusion criteria. Pseudonymised patient data (demographic, clinical and prescription data collected routinely as part of cardiovascular disease prevention and care) will be collected via extraction from routine medical records, facilitated by PRIMIS, at baseline and 7.5- and 15-month follow-up time points. This will be a pragmatic trial, taking place in real practice settings, and it will not be blinded as each GP practice will be aware of which group they have been allocated to. Following baseline data extraction, practices randomised to the enhanced care group will receive the intervention, which will consist of two elements. Firstly, all healthcare professionals working at each practice allocated to the intervention group and with medication prescribing responsibilities within their practice will be invited to complete training concerning contemporary statin prescription recommendations as part of their routine practice learning. At least two healthcare professionals from each participating practice will be required to complete this training. This training will be completed online and will be designed to focus on supporting their patients to achieve suitable statin treatment intensities. The training will be completed at the start of the study, after site-setup for each recruited intervention practice. The researchers will also monitor practices and provide feedback at 3 and 9 months via short remote meetings with practice staff. Each intervention practice will be provided with a helpline phone number,

should they have any questions regarding the training. Secondly, eligible patients within the practices randomised to the enhanced care intervention group will receive monthly reminder text messages designed to support them to regularly take their statin medications as prescribed. These uni-directional texts will contain pre-determined content provided by the study team, and will be sent using pre-existing GP practice text messaging systems throughout the 15-month intervention period. Healthcare professionals operating within practices randomised to the usual care control group will receive no training, and the text messaging system will not be implemented in these practices. GPs attending these practices will be free to make changes to their patients' statin prescriptions, though they will not have access to the healthcare professional training sessions or any associated materials. Eligible patients attending these practices will receive their usual care.

Intervention Type
Behavioural

Primary outcome(s)
Low-density lipoprotein-cholesterol (LDL-C) measured via extraction of routine test results from healthcare records at 0, 7.5 and 15 months

Key secondary outcome(s))
1. Statin adherence measured by the proportion of days covered (PDC) at 15 months post-baseline assessment
2. Statin prescriptions measured by extraction of routine prescriptions from healthcare records at 15 months post-baseline assessment
3. Total cholesterol levels measured by extraction of routine prescriptions from healthcare records at 15 months post-baseline assessment at 15 months post-baseline assessment
4. Adherence to other cardiovascular medications, such as anti-hypertensive medication, measured by the proportion of days covered (PDC) at 15 months post-baseline assessment
5. LDL-C levels in those with vs without co-morbidities (hypertension, chronic kidney disease (CKD), cardiovascular disease (CVD), type 2 diabetes mellitus (T2DM), multimorbidity) measured by extraction of routine prescriptions from healthcare records at 15 months post-baseline assessment
6. Consultation rates measured using audit feedback at 15 months post-baseline assessment

Completion date
31/12/2024

Eligibility

Key inclusion criteria
Practice inclusion criteria:
1. List size of over 6,000
2. A principal investigator (PI), on behalf of the practice, is willing and able to sign the Remote Access Agreement and Organisation Information Document with the University of Leicester for the sharing of pseudonymised patient data, and provide informed consent on behalf of the practice
3. The GP Practice is willing for PRIMIS to carry out a remote database search and data extractions (at 0, 7.5 and 15 months), on behalf of the lead study team at the University of Leicester and in line with the Remote Access Agreement (see Section 8.2)
4. The PI and corresponding GP practice is able and willing (in the investigator's opinion) to comply with all study requirements, including allowing practice staff to attend and complete

study-related training
5. The GP practice is already using an automated text mailing system as part of their routine care
6. The GP practice is using either the EMIS Web or SystmOne clinical database systems.
7. The GP practice is not participating in any cluster trials involving medication adherence

Patient inclusion criteria:
1. Male or female, aged between 18 and 75 years at study initiation
2. Enrolled at an eligible and participating practice
3. Receiving a prescription for any type of statin for at least the last 12 months
4. Displaying hypercholesterolaemia, defined in this instance as a most recent (within the last 24 months) LDL-C result of >3.0 mmol/l
5. Diagnosed with at least one of the following conditions: type 2 diabetes; diagnosed hypertension (coded in their healthcare records); chronic kidney disease (stage 3 onwards – eGFR <60 ml/min/1.73m^2), or cardiovascular disease (comprising ischaemic heart disease, previous myocardial infarction, previous stroke, previous transient ischaemic attack)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
41

Key exclusion criteria
Practice exclusion criteria:
1. The PI is not willing and able to give informed consent
2. The GP practice is not willing and able to sign the OID or Remote Access Agreement
3. The GP practice is not willing to let PRIMIS remotely install electronic software on their system to carry out the database search and data extractions
4. The GP practice is not willing to have clinical staff participate in the training
5. The GP practice is not able and willing (in the chief investigator's opinion) to comply with all other study requirements
6. The GP practice is not using either EMIS Web or SystmOne clinical database systems
7. The GP practice is currently participating in any cluster trials involving medication adherence

Patient exclusion criteria:
1. Aged under 18 years or over 75 years at study initiation
2. Most recent LDL-C result of < 3.0 mmol/l
3. Most recent LDL-C result of < 3.0 mmol/l
4. Receiving prescriptions via electronic repeat dispensing (this invalidates the use of PDC, as

prescriptions are automatically ‘filled’ without input from the patient, therefore invaliding the use of PDC as a surrogate measure of adherence) or routinely using ‘dosset box’ prescriptions (this also impacts adherence and makes adherence difficult to approximate)
5. Receiving end of life or palliative care
6. Patient has opted out of sharing their personal data as part of the national data opt-out policy
7. Patients still on the GP system who have died or left the practice prior to the first data extraction

Date of first enrolment
01/06/2022

Date of final enrolment
31/05/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NIHR CRN: East Midlands
Knighton Street Outpatients
1st Floor
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LE1 5WW

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Government

Funder Name
NIHR Applied Research Collaboration East Midlands

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the study team.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No