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Community pharmacy: highlighting alcohol use in medication appointments

Submission date 17/06/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/06/2019	**Overall study status** Completed	
Last Edited 19/07/2023	**Condition category** Other	

Plain English summary of protocol

Background and study aims
This application is for the pilot trial phase of a five-year research programme, funded by the National Institute for Health Research. The researchers want to find a way of discussing alcohol consumption in local pharmacies, and specifically to see if this works for NHS patients who use existing medicine review services. This research will allow them to consider how this should be rolled out across the country if it works, and what should happen if it doesn't. In the first phase of the programme, the researchers co-produced the intervention with community pharmacists and patients. This study will examine the feasibility of implementing the intervention, called the Medicines and Alcohol Consultation (MAC), and recruiting patients to a trial.

Who can participate?
Patients aged 18 or older who receive medicine review services and are drinking more than is healthy

What does the study involve?
Participating pharmacies are randomly allocated to the intervention group or the control group. For patients in intervention group pharmacies the MAC intervention is incorporated into routine consultations. Pharmacies allocated to the control group continue to provide services as usual.
1. Participants' total weekly alcohol consumption and medications management are measured after 2 months.

What are the possible benefits and risks of participating?
The information from this study will show how pharmacists might be able to help people think about their alcohol consumption and medicines use. There are no known risks to taking part.

Where is the study run from?
Community pharmacies in Yorkshire (UK)

When is the study starting and how long is it expected to run for?
April 2019 to August 2019

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
41747

Study information

Scientific Title
Community pharmacy: highlighting alcohol use in medication appointments (CHAMP-1) pilot study

Acronym
CHAMP-1

Study objectives

The researchers want to find a way of discussing alcohol consumption in local pharmacies, and specifically to see if this works for NHS patients who use existing medicine review services. This research will allow them to consider how this should be rolled out across the country if it works, and what should happen if it doesn't. In the first phase of the programme, they co-produced the intervention with community pharmacists and patients. The pilot trial will examine the feasibility of implementing the intervention, called the Medicines and Alcohol Consultation (MAC), and recruiting patients to a trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/06/2019, South West - Frenchay Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol BS1 2NT; Tel: +44 (0)207 1048 045; Email: nrescommittee.southwest-frenchay@nhs.net), ref: 19/SW/0082

Study design
Randomised; Both; Design type: Process of Care, Education or Self-Management, Complex Intervention, Management of Care, Qualitative

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Unhealthy drinking

Interventions
Pilot Trial
The pilot trial will compare two groups of patients: those who will have the MAC, and those who will have medicines reviews as they are now. A computer will decide into which group a patient goes. The study will be run in 8-12 community pharmacists in Yorkshire, with half selected to use the MAC (also decided by a computer). Pharmacists using the MAC will receive weeks of training and support. This will include audio recording consultations, if the patient agrees, so we can help pharmacists develop their practice. All pharmacists will be trained to do the research before patients are recruited to the study (the aim is to recruit at least 80). Two months after study entry, the researchers will telephone both groups of patients to ask about their drinking, medicine use and health, and because of the way the study is done, any differences between the groups should be due to the MAC. With permission, the researchers will audio-record some

medicines reviews and speak to some patients and pharmacists to help understand how the MAC worked, and how it could be improved for the main study. The researchers will investigate what patient information is held in pharmacies, and if patients agree, access information on medicines and use of health services to assess if this information could be used in the main trial.

Qualitative Study
The researchers will also investigate pharmacists' and patients' engagement with the MAC. This will involve observation of pharmacists training days; three interviews with two pharmacists as they progress through the training; post-training audio recording of at least one consultation from each pharmacist to explore skills development; telephone interviews conducted within one week of these consultations with 1 patient from each intervention site (n=6); interviews with all pharmacists at the end of the study period.

SWAT Sub-Study
The researchers are also proposing to undertake a Study With a Trial (SWAT). A computer will decide if participants who provide a mobile telephone number will be sent a text message about the follow-up interview early (one week prior), late (72 hours prior), with personalisation which includes the recipient's name, or with no personalisation. The researchers will evaluate what difference this makes to the follow-up rate.

Intervention Type
Other

Primary outcome measure
1. Total weekly alcohol consumption, measured using a retrospective diary in the 7 days prior to follow-up at 2 months
2. Medications management, measured using PROMIS Self-Efficacy for Managing Medications and Treatment - 8a at 2 months

Secondary outcome measures
1. Heavy drinking and drinking within recommended weekly guidelines, derived from primary alcohol measure at 2 months
2. Adherence measured by ProMAS at 2 months
3. Anxiety (GAD-7) and depression (PHQ-8) measured at 2 months
4. Quality of life measured by the EQ-5D-5L at 2 months

Overall study start date
08/04/2019

Completion date
07/08/2019

Eligibility

Key inclusion criteria
Patients:
1. Aged 18 years or older
2. Screen positive for unhealthy drinking on a single item alcohol screening question (AUDIT question 1, for frequency of drinking)
3. Using pharmacy medication review services

Any participant in the CHAMP-1 pilot trial who provides a mobile number and agrees on the consent form to receive text messages will be eligible for the text message SWAT.

Pharmacies:
1. Conducting Medicines Use Reviews during the study period
2. Agree to audio record consultations (with patient consent)
3. Agree to participate in training as required, including GCP and informed consent training delivered by Yorkshire and Humber CRN

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 80; UK Sample Size: 80

Total final enrolment
51

Key exclusion criteria
1. Patients in receipt of alcohol treatment in the previous 12 months
2. Participants who do not provide a mobile number or consent to receive texts will be excluded from the text message SWAT

Date of first enrolment
24/06/2019

Date of final enrolment
07/08/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NIHR CRN: Yorkshire and Humber
United Kingdom
S10 2SB

Sponsor information

Organisation
University of York

Sponsor details
c/o Michael Barber
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Sponsor type
University/education

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-0216-20002

Results and Publications

Publication and dissemination plan
1. Peer reviewed scientific journals
2. Conference presentation

Intention to publish date
01/11/2020

Individual participant data (IPD) sharing plan
This is a pilot trial to inform main trial progression. The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/10/2020	16/10/2020	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Using qualitative process evaluation in the development of a complex intervention to advance person-centred practice by pharmacists: The Medicines and Alcohol Consultation (MAC)	01/12/2021	19/07/2023	Yes	No