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Medicines and alcohol consultation programme delivery study

Submission date	Recruitment status	[_] Prospectively registered
17/03/2023	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/04/2023	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/03/2026	Other	

Plain English summary of protocol

Background and study aims
Some people drink alcohol and take multiple prescription medications, which poses risks to their health. This study is part of an NIHR programme grant, led by the University of York, which aims to co-produce with the pharmacy profession and with patients, an intervention discussing alcohol within routine structured medication review (SMR) consultations, delivered by clinical pharmacists in primary care. The SMR specification recognises the risks of alcohol interactions with medicines and thus the potential contribution of clinical pharmacists in addressing alcohol within their clinical practice. The approach encourages practitioners and patients to consider alcohol, not as a standalone issue to be addressed separately, but rather as integral to clinical care. This is because alcohol is another drug, the impacts of which need to be considered within patient-centred discussions about treatments, adherence, particular conditions and wider health and well-being. The medicines and alcohol consultation (MAC) intervention is intended to help patients to think through whether drinking affects their medication use, conditions and health, and to enable pharmacists to skillfully engage with these issues in a person-centred manner. The aim of the study is to examine the delivery of the MAC from the perspectives of participating clinical pharmacists and patients receiving SMRs.

Who can participate?
Patients having an SMR delivered by a clinical pharmacist who has received the MAC practice development programme.

What does the study involve?
The study involves an investigation of the delivery of the MAC programme to study how clinical pharmacists engage and acquire person-centred skills in practice, including alcohol-specific and other challenges faced, and how practice changes or does not. The study will also examine how patients participate in and respond to alcohol discussions within SMRs, their experience of the SMR and wider views on discussing alcohol as a drug linked to their medicines and conditions

What are the possible benefits and risks of participating?
The information from this study will show how clinical 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?
Yorkshire and the North East of England (UK)

When is the study starting and how long is it expected to run for?
September 2022 to December 2023

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

Who is the main contact?
Prof Duncan Stewart (Programme Manager), duncan.stewart@york.ac.uk

Contact information

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Public

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Scientific

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Additional identifiers

Integrated Research Application System (IRAS)

320182

Central Portfolio Management System (CPMS)
54839

Study information

Scientific Title
Medicines and alcohol consultation (MAC) programme delivery study

Acronym
CHAMP-1

Study objectives
The aim is to examine the delivery of the MAC intervention from the perspectives of participating clinical pharmacists and patients receiving structured medication reviews (SMRs) in primary care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/01/2023, North East - Newcastle & North Tyneside 2 Research Ethics Committee (Meeting held by video-conference via Zoom; +44 (0)2071048086, (0)2071048140; newcastlenorthtyneside2.rec@hra.nhs.uk), ref: 22/NE/0237

Primary study design
Observational

Study design
Observational study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Primary care

Interventions
This is an observational study of intervention delivery, looking at the MAC intervention delivered by clinical pharmacists in general practices in Yorkshire & Humber and North East & Cumbria regions.

The study involves the delivery of the 10-week practice development programme comprising two in-person consultation skills workshops, and weekly practice development coaching phone /video calls with the research team that focuses on pharmacists' progress with integrating the MAC approach into structured medication reviews (SMRs). Information on alcohol and medications is also provided.

We will recruit 15 clinical pharmacists whose practice closely resembles the SMR specification guidance (appointments booked in advance, face-to-face, 30 minutes or longer). The pharmacists will receive 10 weeks of practice development training, including workshops, individual coaching, supplementary materials and peer support activities.

During the delivery of the MAC programme, we will closely monitor engagement and practice development for each pharmacist. This will enable in-depth investigations of SMRs as they are delivered, whilst also illuminating the mechanisms by which practice development may or may not change at the level of individual pharmacists. Audio-recorded interviews will be conducted immediately pre- and post-programme on pharmacists' views on their own alcohol-specific and wider SMR practice within their particular GP practice and PCN context. Before the programme, we will investigate how these pharmacists perceive gaps in their alcohol knowledge and skills and their expectations of the programme. Shortly afterwards, they will be asked about the extent to which they are making changes to practice, the reasons for this, and whether they are feeling more confident in discussing alcohol as a drug with their patients. We will also explore how they think the programme complements or advances previous consultation practice training.

Engagement during the programme will be investigated through analysis of observation data on pharmacists at practice development workshops and data kept by coaches to track changes in individual pharmacist practice. Audio recordings of consultations made during the programme will also be used to provide a different strand of evidence on impacts on practice. Pharmacists will be asked to choose two SMR consultation audio recordings from this dataset, which they judge as demonstrating good and less good consultation practice, for discussion at an exit interview.

The MAC programme uses the audio recordings of SMR consultations (with full patient consent) as the key mechanism for self-assessment of developing practice, supported by reviews with coaches. The participating pharmacists will be encouraged to continue this self-assessment practice after completion of the MAC programme. At 3 months, maintenance of changes in SMR practice will be assessed by asking the MAC pharmacists to select another two examples using the same criteria to discuss at a final interview. This interview will investigate views on changing alcohol practice and calibrating consultation competence, as well as the experience of taking on a new role in the system.

Intervention Type
Behavioural

Primary outcome(s)
Patient experiences of the programme measured qualitatively using audio-recorded interviews with a purposive sample (at least one patient per pharmacist) after their SMR to explore the experience of discussing alcohol during the consultation, and their wider views on discussing alcohol as a drug linked to their medicines and conditions.

Key secondary outcome(s)
Pharmacist experiences of the programme measured qualitatively using audio-recorded interviews pre- and post-programme on pharmacists' views on their own alcohol-specific and wider SMR practice within their particular GP practice and PCN context.

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Clinical pharmacists conducting structured medication reviews (SMRs) selected to participate in the MAC programme
2. SMR patients (18+ years) who drink alcohol at least twice per week

Participant type(s)
Health professional, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
28

Key exclusion criteria
1. Clinical pharmacist not conducting SMRs in person
2. Clinical pharmacist not able to conduct sufficient numbers of SMRs
3. Clinical pharmacists not able to attend practice development workshops
4. SMR patients who drink alcohol less than twice per week

Date of first enrolment
20/03/2023

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Humber & North Yorkshire Health & Care Partnership Integrated Care System
https://humberandnorthyorkshire.org.uk
NO COUNTRY SPECIFIED, assuming England
England
N/A

Study participating centre
North East and North Cumbria Integrated Care System
https://northeastnorthcumbria.nhs.uk
NO COUNTRY SPECIFIED, assuming England
England
N/A

Sponsor information

Organisation
University of York

ROR
https://ror.org/04m01e293

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

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 PI: j.mccambridge@ucl.ac.uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/11/2025	30/01/2026	Yes	No
HRA research summary			20/09/2023	No	No