

BMJ Open Theory-based electronic learning intervention to support appropriate antibiotic prescribing by nurses and pharmacists: intervention development and feasibility study protocol

Molly Courtenay,¹ Rosemary Lim,² Rhian Deslandes,³ Rebecca Ferriday,¹ David Gillespie,⁴ Karen Hodson,³ Nicholas Reid,⁵ Neil Thomas,¹ Angel Chater^{6,7}

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For numbered affiliations see end of article.

Correspondence to

Dr Molly Courtenay;
courtenaym@cardiff.ac.uk

ABSTRACT

Introduction Nurse and pharmacist independent prescribers manage patients with respiratory tract infections and are responsible for around 8% of all primary care antibiotic prescriptions. A range of factors influence the prescribing behaviour of these professionals, however, there are no interventions available specifically to support appropriate antibiotic prescribing behaviour by these groups. The aims of this paper are to describe (1) the development of an intervention to support appropriate antibiotic prescribing by nurse and pharmacist independent prescribers and (2) an acceptability and feasibility study designed to test its implementation with these prescribers.

Method and analysis *Development of intervention:* a three-stage, eight-step method was used to identify relevant determinants of behaviour change and intervention components based on the Behaviour Change Wheel. The intervention is an online resource comprising underpinning knowledge and an interactive animation with a variety of open and closed questions to assess understanding. *Acceptability and feasibility of intervention:* nurse and pharmacist prescribers (n=12–15) will use the intervention. Evaluation includes semi-structured interviews to capture information about how the user reacts to the design, delivery and content of the intervention and influences on understanding and engagement, and a pre-post survey to assess participants' perceptions of the impact of the intervention on knowledge, confidence and usefulness in terms of application to practice. Taking an initial inductive approach, data from interview transcripts will be coded and then analysed to derive themes. These themes will then be deductively mapped to the Capability, Opportunity, Motivation-Behaviour model. Descriptive statistics will be used to analyse the survey data, and trends identified.

Ethics and dissemination Ethical approval for the study has been provided by the School of Healthcare Sciences Research Governance and Ethics Committee, Cardiff University. The findings will be disseminated via publication in peer-reviewed journals and through conference presentations.

Strengths and limitations of this study

- To our knowledge, this is the first study to use a theory-based approach to inform the development of an intervention designed to support appropriate antibiotic prescribing by nurse and pharmacist independent prescribers for common, acute, uncomplicated self-limiting respiratory tract infections.
- In line with the Medical Research Council guidance for the development of complex interventions, qualitative evidence, identified in previous research undertaken by the researchers, will inform the intervention.
- The sample size is limited due to the study being centred on acceptability and feasibility in preparation for a future pilot and full randomised controlled trial evaluation.

INTRODUCTION

Multidrug-resistant infections represent one of the greatest threats to human health.¹ Each year in the European Union alone, antimicrobial resistance (AMR) is responsible for an estimated 25 000 deaths and €1.5 billion in extra healthcare costs.² Loss of protection for patients undergoing operations and other medical procedures, prolonged stays in hospital and longer illnesses are each direct consequences of infection with resistant micro-organisms.¹ A leading driver for the growth of AMR is inappropriate use of antimicrobials in humans,³ therefore strategies that support appropriate antibiotic use are important.⁴

Common, acute, uncomplicated self-limiting respiratory tract infections (RTIs) usually resolve spontaneously.⁵ Unless there is serious underlying comorbidity, antibiotics in most cases, have no clinical benefit. However, over 60% of all prescriptions issued

in UK primary care are for RTIs.^{6,7} Their unnecessary use contributes to resistance spread⁸ and in addition, the risk of side effects. The need to conserve antibiotic sensitivity through the management of RTIs without recourse to antibiotics, is a global priority that has been recognised for some time^{8–11} and a key target for interventions is the antibiotic prescribing behaviour of healthcare professionals who manage these infections.

Evidence from systematic reviews of research involving medical prescribers have identified that multifaceted interventions designed to address barriers to change in specific healthcare settings,¹² which involve active clinician education (as compared with passive strategies), the provision of feedback following audit of antibiotic prescribing, and seek to improve prescribing for all respiratory infections as opposed to specific RTIs,¹³ tend towards greater effectiveness. More recent trials, using similar intervention strategies, have demonstrated similar reductions in antibiotic utilisation but have more frequently used electronic learning.¹⁴

In the UK, around 34000 nurses and 8000 pharmacists have the same independent prescribing capability as doctors. These prescribers frequently manage patients with RTIs and prescribe around 8% of all primary care antibiotics dispensed.¹⁵ A broad range of factors influence the prescribing behaviour of these professionals, including relationships with other prescribers and knowledge of current guidelines,^{16–18} diagnostic uncertainty and the clinical condition of the patient^{16 18–20} and patient expectations for an antibiotic.^{16 18 20} Interventions exist for these healthcare professionals to support the various patient-related and medicine-related stewardship activities in which they are involved,²¹ but there are no interventions available specifically to support appropriate antibiotic prescribing behaviour by these groups. Building on this identified gap, we developed an intervention to support appropriate antibiotic prescribing by nurse and pharmacist independent prescribers. The aims of this paper are to describe (1) the development of an intervention to support appropriate antibiotic prescribing by nurse and pharmacist independent prescribers and (2) a feasibility study designed to test its acceptability, practicability, engagement, implementation, understanding and impact with these prescribers.

METHODS AND ANALYSIS

Intervention development

Design

To reduce wasted resource, interventions should follow a systematic development process, and be initially trialled with a small sample size of the target population to assess acceptability and feasibility.²² This systematic approach should have a strong rationale, in which the target outcomes are identified, effective methods are linked and intervention components are made explicit.²³ The Behaviour Change Wheel (BCW) was used to design the intervention. The BCW²⁴ comprises three layers, each

layer needs to be considered to support behaviour change: (1) the determinants of behaviour, considering Capability, Opportunity and Motivation-Behaviour (COM-B); (2) the intervention functions with which to intervene with these determinants; (3) policy categories to support change on a more structural level. The intervention was guided by the three-stage, eight-step approach of the BCW²⁵ described next.

Stage 1: understand the target behaviour

Step 1: define the problem in behavioural terms

The unnecessary use of antibiotics can lead to AMR and the risk of side effects, yet the evidence available suggests that around a third of patients with RTIs are still prescribed antibiotics by nurse and pharmacist prescribers.²⁶ Furthermore, although interventions available that target the antibiotic prescribing behaviour of general practitioners (GPs) could potentially target some of the drivers of behaviour among nurse and pharmacist prescribers, a broader range of factors influence the prescribing behaviour of these prescribers as compared with GPs.¹⁶ Therefore, interventions for GPs are unlikely to target all of these drivers. To intervene with prescribing behaviour, we must first understand these influences.

Step 2: select target behaviour

The target behaviour for this intervention will be ‘appropriate antibiotic prescribing’.

Step 3: specify the target behaviour

A ‘no antibiotic prescribing strategy’ should be adopted by primary care nurse and pharmacist prescribers for common, acute, uncomplicated self-limiting RTIs (including acute otitis media, acute sore throat/acute pharyngitis/acute tonsillitis, common cold, acute rhinosinusitis, acute cough/acute bronchitis).⁵ Therefore, specifically, the intervention will focus on the antibiotic prescribing behaviour of general practice nurse and pharmacist prescribers during face-to-face consultations with patients with these infections.

Step 4: identify what needs to change

In line with the Medical Research Council (MRC) guidance for the development of complex interventions,²² qualitative evidence on the barriers and facilitators to appropriate antibiotic prescribing behaviour will be consulted. Previous work by the team have consulted a sample of nurse and pharmacist prescribers (n=21) who work in primary care and are responsible for managing patients with RTIs.¹⁶ Interview data were analysed inductively and then deductively using 1) COM-B, the hub of the BCW,²⁴ to identify relevant determinants of behaviour, to create a behavioural diagnosis, and then 2) the Theoretical Domains Framework (TDF), to expand the COM-B, to investigate the psychosocial drivers of behaviour from 14 domains (eg, ‘knowledge’, ‘memory, attention and decision processes’, ‘skills’ and ‘social/professional role and identity’), covering a spectrum of theoretical determinants to further understand what needs to be addressed

to support change. The COM-B behavioural diagnosis highlighted issues related to capability, both physical (eg, skills) and psychological (eg, knowledge); opportunity, both social (norms of practice) and physical (time/space) and motivation, both reflective (beliefs such as confidence and intention) and automatic (emotion or habit). The TDF analysis identified 12 domains (knowledge; skills; social/professional role and identity; beliefs about capabilities; beliefs about consequences; goals; reinforcement; memory, attention and decision processes; environmental context and resources; social influences; emotion and behavioural regulation) (table 1) as influencers to antibiotic prescribing behaviour by nurse and pharmacist prescribers,¹⁶ which have been considered in this intervention described in Stage 2.

Stage 2: identify intervention options

Step 5: identify intervention functions

Nine intervention functions (ie, broad categories of means by which an intervention can change behaviour) make up the second layer of the BCW and include: education, persuasion, incentivisation, coercion, training, enablement, modelling, environmental restructuring and restriction.²⁵ The next step towards intervention development involved selecting intervention functions. The components of the COM-B model are linked to intervention functions in a previously published table within the BCW user-guide.²⁵ For several of the COM-B subcategories more than one intervention function can be effective. Drawing from this table, an intervention strategy was determined. Intervention functions selected to be used in this strategy have been identified by applying the appraise criteria (affordability, practicability, effectiveness and cost effectiveness, acceptability, side effects/safety and equity)²⁵ used to make context-based decisions on intervention content (what will actually be delivered) and delivery (how each chosen technique should be delivered), to determinants of behaviour identified from qualitative interviews.¹⁶ Using this process, the intervention functions, 'education', 'training' and 'modelling', were deemed the most appropriate to use, which enables intervention at all levels of COM-B; psychological capability (education, training) and physical capability (training); physical opportunity (training) and social opportunity (modelling), reflective motivation (education) and automatic motivation (training, modelling)²⁵ (table 1).

Step 6: identify policy categories

Seven policy categories (environmental/social planning, communication/marketing, legislation, service provision, regulation, fiscal measures and guidelines), explicitly linked to intervention functions, sit on the outer layer of the BCW and allows for consideration of how the intervention will be delivered.²⁵ For the case of education, training and modelling, several policy categories are recommended, from 'regulation' to 'legislation', however, for this intervention, it is recommended that 'guidelines' and 'communication/marketing' are used, to ensure that

should the training lead to effective outcomes, practice guidelines will include the training for all staff and this will be communicated effectively (table 1).

Stage 3: identify content and implementation options

Step 7: identify behaviour change techniques

Behaviour change techniques (BCTs) are the smallest components of behaviour change interventions that on their own have the potential to change behaviour.²⁷ BCTs selected to be used in the intervention have been identified from an extensive taxonomy of 93 consensually agreed, distinct BCTs.²⁸ Interview quotes from the qualitative work previously conducted by the research group,¹⁶ and coded using the BCT Taxonomy (BCTT) v1,²⁹ gave rise to 40 BCTs that occurred naturally, that is, were used by nurse and pharmacist prescribers when describing facilitators to the target behaviour (eg, holding an 'antibiotic guardian' professional identity; BCT 13.1 identification of self as role model linked to the TDF domain 'social/professional role and identity') or highlighted as barriers to appropriate prescribing (eg, feeling pressure by the patient to prescribe an antibiotic linked to the TDF domain 'social influences' which may require BCT 1.2 problem solving, more social support—BCT 3.1, or restructuring of the social environment—BCT 12.2). The most appropriate BCTs that link to the COM-B constructs and intervention functions 'education', 'training' and 'modelling', identified in steps 4 and 5 above will be used in this intervention (table 1). This is not all BCTs available, but the ones deemed most suitable for the proposed intervention based on the mapping exercises and those identified from predevelopment interviews.

Step 8: identify mode of delivery

We chose the delivery mode of electronic learning as this was identified from interview data¹⁶ as favourable by nurse and pharmacist prescribers, enabling them to participate at a time and place convenient to them. Furthermore, recent trials with GPs using electronic learning, have demonstrated reductions in antibiotic utilisation.¹⁴ The template for intervention description and replication (TIDieR) reporting tool for complex interventions,³⁰ which provides a checklist of the information to include when describing an intervention (including information on the implementation process, activities, their purpose, and timing) was used to ensure the completeness of the description of this intervention.

Description of intervention: electronic learning activity

An electronic learning activity, comprising a typical consultation scenario, in a 5 min interactive animation using a variety of open and closed questions within the e-learning activity will assess understanding, provide information and demonstrate behaviour using the intervention functions education, training and modelling. E-learning has been chosen as the mode of delivery to target barriers related to the 12 domains identified as influencers to antibiotic prescribing behaviour by nurse

Table 1 Proposed intervention content and mode of delivery, mapped from COM-B to the TDF, intervention functions and policy categories (based on Cane *et al*²⁷ and Michie *et al*²⁵), with BCTs selected as the most appropriate targets for the proposed intervention content drawn from predevelopment interviews and based on studies by Michie *et al*^{25,29} and Cane *et al*²⁸

COM-B	Theoretical domain	What needs to happen for the target behaviour to occur	Intervention function	Policy category	BCTs	Intervention content	Mode of delivery
CAPABILITY (psychological)	Knowledge: an awareness of the existence of something	Knowledge of current guidelines	Education Training	Communication Guidelines	4.1 Instruction on how to perform the behaviour 5.2. Information about health consequences 9.1. Credible source	Instructions on prescribing appropriately for RTIs.	Interactive animation with onscreen multiple choice, true/false and open questions embedded at key points.
	Memory, attention and decision processes: the ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives	Ability to weigh up information from guidelines, patient's pre-existing conditions and illnesses present within the local community, and undertake a full examination and point-of-care testing if appropriate, to inform prescribing decisions			1.2. Problem solving 4.1 Instruction on how to perform the behaviour	Information on decision making.	Interactive animation with onscreen multiple choice, true/false and open questions embedded at key points.
	Behavioural regulation: anything aimed at managing or changing objectively observed or measured actions	Be aware of the importance of self-audit as a means of regulating own prescribing behaviour and ways to make changes where necessary			2.3 Self-monitoring of behaviour 1.1 Goal setting (behaviour) 1.4 Action planning	Information on how to self-monitor prescribing behaviour and its importance. Strategies on how to change behaviour where necessary.	Interactive animation with onscreen multiple choice, true/false and open questions embedded at key points.
CAPABILITY (physical)	Skills: an ability or proficiency acquired through practice	Competence in physical examination and communication skills	Training	Communication Guidelines	4.1 Instruction on how to perform the behaviour	Demonstrating how to undertake an appropriate physical examination.	Interactive animation with onscreen multiple choice, true/false and open questions embedded at key points.
					6.1 Demonstration of the behaviour	Demonstrate how to communicate effectively a non-prescribing decision in a patient-centred way.	
MOTIVATION (reflective)	Social/professional role and identity: a coherent set of behaviours and displayed personal qualities of an individual in a social or work setting	Understand personal and professional responsibilities of role	Education Training Modelling	Communication Guidelines	13.1 Identification of self as role model 4.1 Instruction on how to perform the behaviour	Barriers concerning role legitimacy targeted by the provision of evidence about the important role prescribers can have on AMR (eg, antibiotic guardian poster shown).	Interactive animation with onscreen multiple choice, true/false and open questions embedded at key points.
	Beliefs about capabilities: acceptance of the truth, reality or validity about an ability, talent or faculty that a person can put to constructive use	Confidence in prescribing decisions			15.3 Focus on past success 6.1 Demonstration of the behaviour	Target barriers about role adequacy by reflecting how to perform the behaviour, encouraging reflection on successful scenarios and on the outcomes of prescribing decisions.	Interactive animation with onscreen multiple choice, true/false and open questions embedded at key points.
	Beliefs about consequences: acceptance of the truth, reality or validity about outcomes of a behaviour in a given situation	Decrease fear of delivering a no-antibiotic prescribing decision Maintain appropriate level of antibiotic prescribing			4.1 Instruction on how to perform the behaviour 5.1 Information about health consequences 5.3 Information about social and environmental consequences 6.1 Demonstration of the behaviour 1.1 Goal setting (behaviour)	Increasing positive beliefs about a no antibiotic prescribing decision by the provision of evidence on health consequences of overprescribing, and demonstrating an effective consultation with the target behaviour. Creating a no-prescribing goal for RTIs.	Interactive animation with onscreen multiple choice, true/false and open questions embedded at key points.
MOTIVATION (automatic)	Goals: mental representations of outcomes or end states that an individual wants to achieve				2.2 Feedback on behaviour	Feedback from peers.	Interactive animation with onscreen multiple choice, true/false and open questions embedded at key points.
	Reinforcement: increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus	Use of audit and feedback to maintain appropriate level of antibiotic prescribing			11.2 Reduce negative emotions 5.6 Information about emotional consequences 5.4 Monitoring of emotional consequences	Using a no-prescribing scenario, thought to induce negative emotion and providing strategies to meet the target behaviour without upsetting the patient and inducing practitioner negative emotion.	Interactive animation with onscreen multiple choice, true/false and open questions embedded at key points.

Continued

Table 1 Continued

COM-B	Theoretical domain	What needs to happen for the target behaviour to occur	Intervention function	Policy category	BCTs	Intervention content	Mode of delivery
OPPORTUNITY (physical)	Environmental context and resources: any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence and adaptive behaviour	Use of resources to communicate prescribing decisions	Training	Guidelines	4.1 Instruction on how to perform behaviour 7.1 Prompts and cues 1.2 Problem solving	Instructions on how resources can be used (eg, patient information leaflets, posters, etc) to effectively communicate prescribing decisions.	Interactive animation with onscreen multiple choice, true/false and open questions embedded at key points.
OPPORTUNITY (social)	Social influences: those interpersonal processes that can cause individuals to change their thoughts, feelings or behaviours	Effectively manage patient expectations for an antibiotic	Modelling	Communication	1.2 Problem solving 1.1 Goal setting (behaviour) 5.1 Information about health consequences 3.1 Social support (unspecified) 12.2 Restructuring the social environment 6.2 Social comparison	Information on patient-centred strategies (including the support of other prescribing colleagues) that can be used to deal with patient expectations.	Interactive animation with onscreen multiple choice, true/false and open questions embedded at key points.

AMR, antimicrobial resistance; BCT, behaviour change technique; COM-B, Capability, Opportunity and Motivation-Behaviour; RTI, respiratory tract infection; TDF, Theoretical Domains Framework.

and pharmacist prescribers.¹⁶ The activity can be used as a standalone resource, or can be added to a larger online package. Using elements of gamification by way of a 'spot the difference' format, the animation comprises two separate consultations by a prescriber with an adult presenting with a common, acute, uncomplicated self-limiting RTIs; a 'non-congruent', followed by a 'congruent' consultation towards non-prescribing behaviour. In the first animation, BCTs and communication skills that would facilitate nurse and pharmacist prescribers to reach a no antibiotic prescribing decision (described in step 7 above) are absent; a 'non-congruent' consultation. In the second animation, a motivational interviewing style³¹ is taken to lead to a patient-centred and 'congruent' approach highlighting the need to engage the patient in the consultation process, resist telling them what will not work, focus on strategies to optimal treatment, understand the patient's perspective, evoke a sense of empowerment, ensuring that the patient feels practitioner support and has a plan going forward,³² which one would hope would lead to a more effective consultation.³³ Although evidence from a systematic review of the utility of gamification as a teaching strategy for health professionals is unclear,³⁴ there is some evidence that online games can improve health professionals' knowledge of sepsis management³⁵ and their overall use of antibiotics.³⁶ In order to stimulate active learning, users are presented at various points throughout the animation with a variety of interactions that focus the user's attention on the differences between the two consultations. Points are scored for each correct answer. Key points are summarised at the end of the second animation, imparting factual information.

Acceptability and feasibility study

Intervention delivery using digital technology has resulted in very different patterns of engagement, with intervention users having the ability to access intervention support when they require it. When developing and evaluating digital interventions, consideration needs to be given to the relationship between the 'micro' level of immediate engagement with the digital dimension of the intervention and the 'macro' level of engagement with long-term behaviour change.³⁷ Effective engagement to achieve behaviour change must be empirically established in a particular intervention context and for any particular user as this is likely to differ for different types of interventions and target behaviours.^{38 39} A user-centred and iterative cycle of development and testing is recommended^{38 39} and will be used in this study with the use of mixed methods to measure effective engagement, combining objective assessment of technology usage, behaviour and reactions to the intervention with qualitative reports of user experience.³⁸ Such an approach will ensure digital intervention content and delivery is pre-adapted during development to anticipate a range of user reactions and so improve engagement.³⁸

Participants

The feasibility and acceptability of the intervention will be tested on a sample of general practice nurse and pharmacist prescribers (n=12–15), who manage the care of patients with RTIs, who have participated in previous research by MC.¹⁶ If there are insufficient participants, members of the research team (KH and RL) will approach key contacts in their existing nurse and pharmacist prescriber networks to help with recruitment.

Recruitment

Prescribers will be contacted via email and invited to participate in a pre-post online questionnaire, the intervention and a semi-structured interview. Those who agree to participate, will be sent recruitment materials (participant information sheet and consent form), and followed up with a telephone call by a researcher in which they will have the opportunity to ask any questions they may have prior to consenting to take part. Recruitment will continue until a minimum of 12 participants (maximum 15 nurse and pharmacist independent prescribers) have been recruited. As in previous studies,^{16 26} it is expected that this sample size will enable data saturation to be achieved to understand the feasibility and acceptability of the developed intervention.

Procedure and data collection

Participants will be sent the link to the intervention, which can be accessed on any internet-enabled device, and encouraged to engage with all its components. Data collection will comprise qualitative (semi-structured telephone interviews) and quantitative (pre-post online questionnaires) methods.

Qualitative methods are crucial to fully understand and interpret user experiences, capturing critical information about how users react to the content, design and delivery of the intervention⁴⁰ and the wider social and contextual influences on engagement.⁴¹ Such an approach is central to participatory user-centred design, which is the key to developing and evaluating digital interventions in order to ensure that they are engaging and effective.³⁸ Interviews, conducted by RL, will take place within a 2-week period following participants' use of the online resource to aid recall of specific perceptions of using the intervention. A generic topic guide will address user experience of the intervention and will aim to understand how the intervention influences each component of the TDF that was delivered within the intervention (ie, knowledge; skills; social/professional role and identity; beliefs about capabilities; beliefs about consequences; goals; reinforcement; memory, attention and decision processes; environmental context and resources; social influences; emotion and behavioural regulation). This will provide insight into the key issues associated with the specific mechanisms through which the intervention operates, and the barriers and enablers to its uptake in addition to its usability, in terms of how easy it was to use the intervention. All interviews will be digitally audio-recorded and

transcribed verbatim and any identifying information removed.

When evaluating the effects of digital technology, the application of research methods that provide insights into the unique characteristics of the intervention are recommended.³⁸ Using an online questionnaire design completed before and immediately after the intervention, developed from the findings of previous work,²⁶ data will therefore also be collected to assess participants' perceptions of the impact of the intervention on a) knowledge and confidence, and b) its usefulness. The preintervention questionnaire will consist of six items to assess confidence to: gain information on patient expectations, support patients, build rapport, communicate effectively, see and examine different viewpoints, ensure patients both understand and are happy with the prescribing decision. Each of the items will be assessed using a 5-point Likert scale for response options (strongly disagree to strongly agree). Response to the items will be summed for an overall score which could range from 6 to 30 with higher scores indicating higher confidence. Demographic details including type of prescriber (ie, nurse or pharmacist), length of time qualified as a prescriber, time in current post, clinical setting, length of consultation time will also be collected.

The postintervention questionnaire will include identical questions to the preintervention questionnaire, and additional questions designed to explore the usefulness of the intervention, that is, whether the information was known to participants, its applicability to practice, if it makes them feel more comfortable when speaking with patients and if it encourages participants to consider how they would apply the information to practice and think differently.

Analysis

NVivo⁴² will be used to code and categorise interview data. Analysis will be informed by the principles of thematic analysis.⁴³ This will enable both predetermined and identified issues to be explored in depth while using the COM-B model as an explanatory framework. Initial coding will be carried out by one researcher (RL) and themes discussed and agreed on with a second researcher (MC). Initial codes and identified themes will be reviewed by a third qualitative researcher with expertise in the BCW (AC) and mapped by this researcher to the appropriate domains of the COM-B model with ongoing discussion with RL.

Descriptive statistics will be used to analyse the data collected via the questionnaire surveys, to identify any emerging trends in knowledge and confidence.

Patient and public involvement

Patients were not involved in the development of the research question, outcome measures, design of the study or, recruitment to, and conduct of, the study.

ETHICS AND DISSEMINATION

The reaction of participants to the content and mode of delivery of the intervention, its acceptability and usability will be evident from the findings. If findings are positive, any suitable amendments will be made. Once we are confident that the intervention can be implemented with high fidelity, that any future developments can be considered relatively minor and that it leads to improved outcomes, the work will move to a pilot and cluster randomised controlled trial. The results of the study will be published in peer-reviewed journals and presented at national and international conferences.

Author affiliations

- ¹School of Healthcare Sciences, Cardiff University, Cardiff, UK
²School of Pharmacy, Reading University, Reading, Berkshire, UK
³School of Pharmacy and Pharmaceutical Sciences, Cardiff University, Cardiff, UK
⁴Centre for Trials Research, Cardiff University, Cardiff, UK
⁵Public Health Wales, Cardiff, UK
⁶University of Bedfordshire, Centre for Health, Wellbeing and Behaviour Change, Bedford, UK
⁷University College London School of Pharmacy, London, UK

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