University of East Anglia

The role of community pharmacy in diabetes prevention

(Volume 2 of 2)

Ms. Thando Katangwe, MRPharmS, PGDip, MSc

Submitted for the degree of Doctor of Philosophy

University of East Anglia

School of Pharmacy

November 2019

List of appendices

Appendix 3.1

Protocol for mixed methods study (Chapter 3) and nominal group technique study (Chapter 6)

Appendix 3.1:
Protocol for mixed methods study (chapter 3)
and Nominal group group technique study (Chapter 6)

University of East Anglia

The community pharmacy setting for the delivery of diabetes prevention programmes: a mixed methods study in people with 'prediabetes'

Chief investigator
Thando Katangwe (T.Katangwe@uea.ac.uk)
PhD Student, School of Pharmacy, University of East Anglia.

Research supervisors
Dr M. Twigg (M.Twigg@uea.ac.uk)
Lecturer in Pharmacy Practice, School of Pharmacy, University of East Anglia.

Dr J. Sokhi (J.Sokhi@uea.ac.uk)
Lecturer in Pharmacy practice, School of Pharmacy, University of East Anglia.

Dr C. Kirkdale (charlotte.kirkdale@boots.co.uk)
Health Outcomes Research Manager | Pharmacy Contract Framework & Outcomes, Boots UK.

Protocol No.	Revision	Date	Investigator Sig.	Sponsor Sig.
TK-MT-Rev4	4	15.12.2018	T.K.	MK

1.0 Introduction

Diabetes mellitus is one of the most common non-communicable diseases responsible for the major health and development challenges of the 21st century [1]. It remains one of the leading causes of death in most developed countries and a financial burden to many health economies [2, 3]. In England, 3.8 million people are estimated to be living with the condition, with 90% of all cases attributable to type 2 diabetes [4]. The National Health Service (NHS) in England spends approximately £8.8 billion a year (10% of the total NHS budget) on the management of diabetes and its complications [5]. In addition, five million people in England are estimated to have 'prediabetes', a term used to denote blood glucose levels above normal range but not high enough for diagnosis of type 2 diabetes [6, 7]. Prediabetes is not a clinical entity in itself, but rather denotes an increased risk of developing type 2 diabetes. The risk of developing type 2 diabetes depends on multiple risk factors, of which obesity is most significant [8]. Obesity accounts for approximately 80-85% of the overall risk of developing type 2 diabetes and together with physical inactivity, are estimated to cause the large proportion of the global diabetes burden [9, 10].

Central to the approach for the prevention of type 2 diabetes is the promotion of healthy diet and exercise to reduce the rise in obesity [11-13]. Evidence suggests that if individuals at high risk are identified before overt diabetes develops and intensive lifestyle interventions are implemented, the onset of type 2 diabetes may be delayed or even prevented [14, 15]. In England, the NHS Diabetes Prevention Programme (DPP) has been developed in view of such evidence [16]. The effectiveness of lifestyle based DPPs was initially demonstrated in several large randomised controlled trials and subsequently by smaller translational studies [17-22]. Translational research has shown pragmatic interventions, delivered across diverse settings and populations to be effective in terms of weight loss [21, 22] and delaying the incidence of type 2 diabetes [23-28]. A sustained lifestyle change has been highlighted as the key to success in DPPs, with greatest benefits observed with highest compliance and achievement of targets (weight loss and diet) [29]**.** However, due to low participation rates attributed to either non-eligibility, refusal to participate or attrition, the population level impact of DPPs has often been criticised [28-30].

Primary care based interventions have been associated with the lowest attrition and highest reach to the targeted populations [7, 30, 31]. The National Institute of Health and Care Excellence (NICE) recommend the delivery of intensive lifestyle programs by primary health care teams including community pharmacies [7]. However, most pragmatic studies have been conducted in primary care settings such as GP practices, with very little research exploring a community pharmacy setting [30, 31]. Over recent years the traditional dispensing role of community pharmacists has developed towards the delivery of public health services such as diabetes screening, smoking cessation and weight reduction programmes [32-36]. This is primarily due to accessibility. Intervention accessibility has been highlighted amongst the barriers of participant engagement in disease prevention programs. Laws *et al*. who explored factors influencing participation in a practice based vascular disease prevention program highlighted accessibility barriers such as transportation and geographical location [37]. In addition, they highlighted challenges in organising group based sessions suitable to most of the participants and identified the need for flexibility including

delivering night time, weekend or individual sessions and telephone follow-up [37]. Kullgren *et al*. who examined engagement of people found to have prediabetes following work based screening identified primary reasons for not engaging as work and social commitments and accessibility of exercise facilities [38]. Similar social barriers were also highlighted by Penn *et al.* who aimed to understand the experience of participants who maintained behaviour change following a lifestyle intervention [39].

Intervention barriers such as accessibility, work and social barriers highlighted by qualitative research to date could be addressed by using the community pharmacy setting. The community pharmacy, as the most visited NHS care setting in England, is accessible to approximately 90% of the population within a 20-minute walk [40-42]. The availability of a private consultation room within the majority of the community pharmacies (90%) in England and the long opening hours including weekends, makes them a flexible setting for the delivery of public health services such as the DPP [32, 35]. The limited space to facilitate group based care within the community pharmacy setting may present a flexible alternative for the delivery of individualised, weekend and night time sessions [31]. Additionally, potential facilitators to engagement such as face to face interaction with professionals [39, 43] and continuity of providers [31, 44] are highly applicable to community pharmacy.

In England, the accessibility of community pharmacies increases to over 99% in highly deprived populations including lower socioeconomic groups, males and ethnic minority groups [42]. In these populations, obesity, the greatest modifiable risk factor of type 2 diabetes, has been shown to have the highest prevalence [45, 46]. Research investigating barriers and facilitators to engagement in different ethnic backgrounds such as South Asians [44], Hispanic [47], Black Africans [48] and Bangladeshi [49] has highlighted common barriers as language [44, 47, 49], social roles including faith based responsibilities [44, 49] and poor cultural and religious understanding of healthcare professionals [32, 49, 50]. With evidence showing that DPPs can be successfully delivered by lay personnel, pharmacy support staff could play an important role in engaging ethnic minorities and other hard to reach groups as they tend to reflect the culture of the local population [21].

Current qualitative research has highlighted important barriers and facilitators to engagement that may be addressed by delivering lifestyle interventions in the community pharmacy setting. However, despite recommendations by NICE for community pharmacies to offer lifestyle interventions, there is inadequate research exploring their role in the prevention of diabetes. Additionally, to date research has primarily focused on obtaining the views and perceptions of intervention providers [37] or people who engage with the programmes [37, 39]. Despite reported high levels of non-engagement (30-46%), there has been little to no involvement of those who haven't engaged [37, 39]. Although the research carried out by Kullgren *et al* explored non-engagement, findings may not be applicable since participants were not referred to a particular intervention and engagement varied from attempting to lose weight, achieving exercise recommendations to having discussed a pharmacological intervention with a primary care provider [38]. Therefore, to facilitate the design of a community pharmacy based DPP that could also benefit those who are unlikely to attend group based DPPs there is a need to further explore non-engagement and

perceptions in the targeted population. The aim of this research is to quantitatively explore uptake in the current NHS DPP and to build on present qualitative research on the barriers and facilitators to engagement in DPPs in order to inform the design of a pharmacy based intervention. Patient questionnaires will be used to elicit data on current intervention uptake and gather general views on the community pharmacy. Focus groups and structured interviews will then be conducted to further explore the main barriers to intervention uptake and elicit views that will aid the design of a pharmacy based DPP.

2.0 Aim and Objectives

2.1 Aim

To inform the design of a community pharmacy-based DPP by exploring factors influencing engagement with the current NHS DPP and eliciting views and perceptions on the role of the community pharmacy in prediabetes.

2.2 Objectives

1 To characterise participation in the current NHS diabetes prevention program in Norfolk and Norwich.
2 To describe the barriers and facilitators of engagement in people who enrol and those who do not enrol in DPPs.
3 To describe views and perceptions of people with prediabetes on a community pharmacy-based DPP.
4 To develop a model for a community pharmacy based DPP.

3.0 Methodology, Procedure and Analysis

Ethics and governance approval will be obtained from the Health Research Authority before commencing the research. Consent will be sought from the primary gatekeepers which are GP practices participating in the screening and referral for the Healthier You NHS DPP in Norfolk and Norwich. Please refer to appendix 1 for a summary of the methodology of this study.

The Healthier You: NHS DPP Structure

The NHS DPP is nationally commissioned and funded by NHS England. The programme was initiated in 2016 with a first wave of 27 areas, with an expectation to roll out to the whole country by 2020. The programme identifies people at high risk of type 2 diabetes and refers them onto a behavioural change intervention offering tailored, personalised help to reduce risk via education, weight loss and exercise. The intervention offers at least 13 education and exercise sessions of one to two hours, at least 16 hours face to face or one-to-one in total over a minimum of 9 months. The programme is nationally provided by four providers (Reed Momenta, ICS Health and Wellbeing, Health Exchange CIC and Ingeus UK Limited) who were selected following a national commercial procurement that was conducted in 2015. In Norwich and Norfolk, one of the first wave areas chosen to deliver the NHS DPP, the service is currently being provided by ICS Health.

Current NHS DPP identification process

People at high risk of type 2 diabetes are primarily identified for referral to the programme by their GP during routine primary care appointments or through retrospective screening of GP databases. Eligible individuals are patients who are 18 year or over and have had an HbA_{1c} blood test within the prediabetes range (42-47mmol/mol (6.0-6.4%)) in the last 12 months [7]. Following identification, individuals are sent letters communicating their risk and inviting them to participate in the NHS Healthier YOU programme in order to lower the risk of developing type 2 diabetes [51]. At this point patients can voluntarily enrol onto the programme by contacting the programme organisers via a telephone number highlighted in the referral letter. GP practices then keep track of individuals identified through screening by assigning read codes for each activity relating to the patient e.g. identified as having prediabetes, referral letter sent, declined participation, enrolled and attending, dropped out or completed. This research will involve sending a questionnaire to people identified through retrospective screening in GP practices and as part of the questionnaire people will be given an option to opt into the participation of interviews or focus groups.

3.1 Participant recruitment

Recruitment methods

Recruitment will take place via participating General Practices which will be identified via Local Clinical Research Networks or CCGs. The chief investigator (TK) will contact the nominated lead at each participating practice to organise the identification process. GP databases will be searched for all individuals identified as having prediabetes since the initiation of the program in 2016 and referred onto the NHS Healthier YOU DPP. Participants will be recruited based on the following inclusion and exclusion criteria:

Inclusion criteria

- Age: >18 years
- Registered to GP practices in Norfolk or Norwich
- Identified as having prediabetes through practice-based screening
- Referred to the NHS DPP Healthier You programme

Exclusion criteria

- Non-English speaking
- History of type 2 diabetes
- Unable to give consent

Practice staff will identify these potential participants using previously conducted searches or read codes attached to patients' records in line with NHS DPP policy. This will simplify the participant identification process for practices. All patients that meet the inclusion/exclusion criteria will be invited to participate. GP practices will then mail out a covering letter (appendix 2), a questionnaire (appendix 3) and a pre-paid envelope (where appropriate) using routine practice mailing procedures (which could include electronic communication e.g. e-mail or text). Each practice will be assigned a specific code which will serve as a practice identifier on the questionnaire. This process will assist in uploading

recruitment to the portfolio if the study is adopted by the Local Clinical Research Network. Information identifying potential participants will not be released to the research team at this stage and they will not be aware of which patients have been sent the information.

3.2 Data collection methods

3.2.2 Questionnaire

Initial data collection will be undertaken using a questionnaire (appendix 3) that will be distributed to eligible participants. The use of questionnaires will allow the collection of demographics, enrolment data and general views on a community pharmacy based DPP. The use of the questionnaire has been adopted in this study as the most efficient way, in terms of time and cost, to obtain data from a large sample from a wide geographical distribution [52]. It also provides anonymity and thus may encourage honest answers [52].

The questionnaire cover/invitation letter will be regarded as the participant information sheet and the completion of the questionnaire regarded as implied consent [53]. This is in accordance with the NHS Medical Research Council and Health Research Authority guidance on consent and participant information sheet preparation [54]. The questionnaire will also be used as an expression of interest form to identify individuals willing to participate in interviews or focus groups. This is to ensure confidentiality and information governance rules are adhered to and that potential participants to this phase of the study are not approached without providing consent.

3.2.3 Interviews and focus groups

Participants who have expressed interest to participate in further research will be allocated to either a focus group or an interview according to their choice indicated in section 4 of the questionnaire (appendix 3). Semi-structured interviews will be conducted to facilitate the understanding of influences in participant's decisions with regards to engagement in DPPs and perceptions of the role of the community pharmacy in the prevention of type 2 diabetes. Understanding motivations and decisions require detailed personal accounts that an interview allows [55]. Semi-structured interviews will be adopted rather than open ended interviews to facilitate the gathering of focused subjective textual data [55]. In order to provide a more accessible option to the studied population an option of either face to face or telephone interviews will be given [55]. Focus groups have been chosen to complement data collected from the interviews, allowing the generation of data from the interaction of participants' views and perceptions in reflection of the group discussions [55]. Here the interaction of the researcher will have less of an influence than in one-to-one interviews, allowing data and insights to be generated from a social context [55]. Using both interviews and focus groups will also provide a degree of triangulation and will give people more choice.

3.3 Data collecting procedures

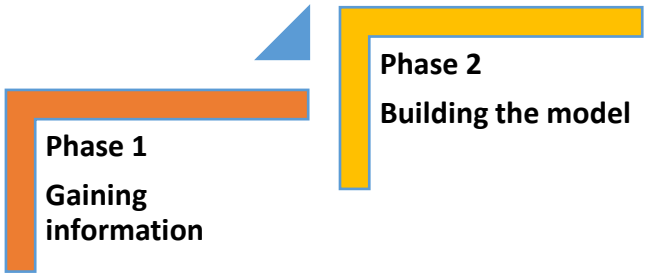
Once completed questionnaires have been returned to the research team, participants who have expressed willingness to be contacted for further research will be identified. The

research team will send interested participants a covering letter (appendix 4) and an information sheet (appendix 5) which will provide more information about the interviews/focus groups. Potential participants will be given two weeks to read the information sheet before making the final decision to participate in the research. Potential participants will then be contacted by the research team to confirm participation and assist the arrangement of a suitable time for the interview/focus groups. Following this, participants who have opted for telephone interviews will also receive a consent form (appendix 6).

An iterative data collection process will be adopted for the qualitative aspect of the study (Fig 1). Data collection will be conducted in two phases. The first phase will be used to gain in-depth information about the main barriers and facilitators of engagement and perceptions on the role of the community pharmacy in diabetes prevention. This phase will consist of one focus group and up to 10 interviews and will be made up of a different set of participants in order to promote triangulation of findings.

The second phase will primarily focus on developing a community pharmacy-based DPP model by building on the findings from the initial phase and the questionnaire. This phase will consist of one focus group and will use the Nominal Group Technique (NGT). The NGT is a consensus method, often applied in research that is directed at the identification of research priorities [56]. The method aims to achieve a general agreement or convergence of opinion around a particular topic [57]. Therefore, adopting this method at this stage will assist in prioritising research items for the modelling process.

Figure 1: Interview and focus group iterative data collection process.

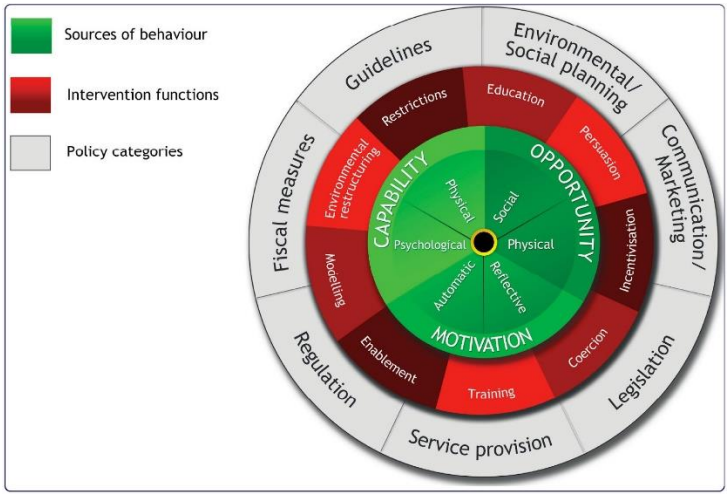


3.3.1 Interview and focus group topic guides

Behaviour change is the key to improving health outcomes. In people with prediabetes, behaviour changes such as diet modification and increasing physical activity may be influenced by multiple factors e.g. motivation, culture and knowledge [37, 38, 49]. The UK Medical Research Council advocates the use of existing evidence, theory and new primary research e.g. interviews with stakeholders, when developing a complex intervention [58]. The use of theory is recommended for consideration at an early stage of the development process in order to aid the understanding of the likely process of change [58]. In this research, the topic guide for the interviews and focus groups will be underpinned by the COM-B model proposed by Mitchie et.al [59]. This model proposes that people need Capability, Opportunity and Motivation to perform a behaviour and was developed to gain

the understanding of behaviour in context and develop behaviour targets as a basis on intervention design. The COM-B model forms the hub of a Behaviour Change Wheel developed from 19 frameworks of behaviour change identified in systematic literature review (see figure 2) [59]. COM-B (the hub of the wheel) identifies sources of behaviour that could be fruitful target for intervention. In this study the interview and focus group topic guide has been underpinned by the COM-B model in order to identify barriers and facilitators to the pathways of change that are likely to influence the targeted behaviour change.

Figure 2: The Behaviour Change Wheel



3.3.2 Semi-structured interviews

Semi-structured interviews will be conducted by the chief investigator (TK) and will take up to a maximum of 1 hour. According to Blaxter et al this is the adequate time to obtain quality and rich interview data [60]. Face to face interviews will be conducted at the University of East Anglia in a private office. Interviews will be audio recorded using two recorders and to facilitate the interviews a semi-structured topic guide will be used (appendix 7). The participants will be informed by the researcher when the recorders are switched on and off. The researcher will also take fields notes following every interview in order to assist analysis and to demonstrate reflexivity.

Following introductions, the researcher will introduce the research topic explaining the aims and objectives of the research, the purpose of the interview and what the interviewer will cover. Before seeking informed written or verbal consent (appendix 6) the researcher will again explain the voluntary nature of the research and arrangements for confidentiality. Participants involved in telephone interviews will be asked to give recorded verbal consent following the researchers reading of the statements on the consent form that would have been sent out to them earlier. Following the interview the researcher will thank the participant and explain what happens next with the data and reporting. At this time any questions raised by the interviewee will be addressed and contact details for information and support services will also be given. Each participant will be given a £10 voucher as a thank you for participation and those involved in face to face interviews conducted at the University will be reimbursed for transportation.

3.3.3 Focus groups

Focus groups will be conducted by two members of the research team (TK and MT) and will last approximately 90 minutes. The venue of the focus group will be arranged by the research team ensuring location convenience and privacy e.g. university meeting room or a location convenient to the participants. Focus groups will be arranged at a time that is convenient for most of the participants. The discussions will be audio recorded using two recorders. Two topic guides (appendix 8 and appendix 10) will be used to facilitate the discussion for the two phases (respectively) with probing questions to ensure that issues relevant to the research topic are covered in depth. Participants in phase 2 will be provided with research findings before the focus group to assist in the ranking process of the Nominal Group Process.

Following introductions, the researcher will introduce the research topic explaining the aims and objectives of the research, the purpose of the focus group and the topics that will be discussed. Before seeking informed written consent (appendix 6) the researcher will again explain the voluntary nature of the research and arrangements for confidentiality. The researcher will also explain that information discussed within the focus group should be regarded as confidential and should not be repeated outside. The researcher will also communicate the ground rules, stressing the importance of not talking over one another to allow the full account of the discussion to be captured by the audio recorders. The participants will be informed by the researcher when the recorders are switched on and off. The role of the researcher will be to encourage an open interactive discussion but also control the discussion to bring everyone in, prevent dominant participants and steer group away from irrelevant topics. Following the discussion the researcher will thank the participants and explain what happens next with the data and reporting. At this time, any questions raised by the participants will be addressed and contact details for information and support services will also be given. Refreshments will be provided and participants will be given a £10 voucher as a thank you for participation and will be reimbursed for transportation. The researcher will also take fields notes following every focus group in order to assist analysis and to demonstrate reflexivity.

Nominal Group Technique focus group procedures

Step 1: Individual responses (15 minutes)

Participants will be informed of the purpose of the focus group (i.e. to determine the most important factors that would influence engagement with community pharmacy-based diabetes prevention services (DPS)) and will be given a brief description of the NGT process via e-mail [56]. Participants will also be provided with the topic guide for the discussion (Appendix 10) including a list of factors identified in phase 1 and will be asked to rank in order of importance what factors would enhance the capability, opportunity and motivation to engage with community pharmacy DPS. The participants will be asked to e-mail their responses to the facilitator prior the group discussion. The ranking process will be anonymous.

Step 2: Discussion (Round robin and clarification) (30-40 minutes)

On the day of the focus group, the facilitator will ask one participant at a time to talk about their ranking to the group in a 'round robin' fashion. Participants will then be asked to discuss the rationale behind their ranking with the group as this helps to highlight any ambiguities in the statements that may have affected response and therefore subsequent consensus [56, 57].

Step 3: Re-ranking responses (10-20 minutes)
At this point the participants would have had the opportunity to reconsider their ranking in light of other participants' views. The facilitator will summarise the main discussion points and provide participants with a ranking sheet, where they will be asked to select their top preferences now that they would have had the chance to consider other views. The ranking process will be anonymous.

3.3.4 Sampling
A maximum of 30 interviews and 3 focus groups will be conducted. To gain the perspective of both engagers and non-engagers in the NHS DPP, a purposive sample based on the characteristics outlined in the questionnaire response will be used. We will aim to hold three focus groups of 6 to 8 people ensuring a group composition that will aid discussion and ensure an element of diversity to help generate richer discussion [55]. Diversity will be sought using age, gender, ethnicity and employment status since sociodemographic factors of the group can influence how open or full the discussion will be [55]. Participants that have expressed an interest but are not sampled for inclusion will be sent a thank you letter (appendix 9) stating that they will not be required to take part.

3.4 Data analysis

3.4.1 Questionnaires
Questionnaire data will be analysed quantitatively. A descriptive analysis of participant demographics will be carried out using SPSS. Data will be explored to identify the distribution of patients' enrolment with respect to age, gender, ethnicity and employment status. Appropriate statistical tests will also be employed to examine how the NHS DPP was rated by participants in terms of those who engaged with the programme and those who haven't. Similarly, we will employ appropriate statistical tests to examine the views of the participants on a community pharmacy based DPP. Views on the community pharmacy will be analysed using content analysis and will inform the qualitative data collection phase.

3.4.2 Interviews and focus groups
Interviews and focus group recordings will be transcribed verbatim by a member of the research team or a transcription company and inputted into NVivo where it will be analysed using thematic analysis, a method for identifying, analysing and reporting themes within data [61, 62]. This approach has been adopted because it can be used to analyse data from different types of communication media, providing a flexible approach to analyse data from both audio recorded interviews and focus groups [61]. To provide an

iterative process of analysis that will be conducted following each phase the data collection procedure, Braun and Clarkes 6 phases of thematic analysis will be used [62].

Step 1: Familiarisation
Interview data will be transcribed verbatim by a member of the research team and/or a transcription company. The transcripts will be checked by another member of the research team. Any disagreements will be resolved by consensus referring back to the original recordings. The researcher will read and re-read each transcript to gain an overview of the content and identify topics and subjects that are of interest and that are linked to the research questions.

Step 2: Inductive coding
Data from the transcripts will be re-read and carefully analysed in order to develop codes according to the research question. The transcribed data will be coded by the main researcher (TK) and checked by another member of the research team. Any disagreement will be agreed by consensus, referring back to the original recordings.

Step 3: Development of themes
Relationships between the codes will be sought in order to develop themes. The development of themes will be aided by the COM-B model and the research questions. Themes will be developed by the main researcher (TK) and for confirmability themes will be checked by research supervisor (MT).

Step 4: Reviewing themes
Transcripts will be re-read by the main researcher (TK) to ensure that correspondence and accuracy between the developed themes and the data. At this point iterative judgements may be made in order to give a more accurate description of the themes e.g. extracts may be moved to other codes and themes. The researcher will also use field notes to assist the accurate description of the themes.

Step 5: Defining themes
Each theme will be given a name which captures the essence of the contents and a detailed analysis of each theme will be written. Transcripts will again be revisited to identify representative extracts to use in the written analysis of each them.

Step 6: Reporting
A clear and concise narrative of the themes will be written using extracts identified in step 5 as illustrative evidence of the themes. This will ensure authenticity of the findings.

Any qualitative data generated from the written sections of the questionnaire will be analysed with the data from the first phase of the qualitative data collection process. Codes and themes generated from each phase will contribute to the development of a community pharmacy-based model.

3.4.2.1 Nominal Group Technique ranking

The scores of the ranking will be totalled by the research team in order to identify research topics that will be taken forward to assist the development of community pharmacy-based diabetes prevention services [63]. Following the identification of research items, the research team will use the COM-B model to identify intervention functions and consequent

behaviour change techniques that could be adopted by the community pharmacy team in order to promote engagement among people with pre-diabetes [59].

3.4.3 Under-representation of non-engagers following questionnaire responses

The focus of this study is primarily to address factors influencing engagement in diabetes prevention programmes. The study will therefore seek to have a good representation of people who haven't engaged with the current NHS diabetes prevention programme. In order to ensure that the views and perceptions of non-engagers are adequately considered we will carry out a preliminary analysis on the questionnaire data to establish whether or not this population is adequately represented.

Where this population consists of less than 20% of the questionnaire responses, we will seek to explore options to increase the representation by specifically targeting this population. We will do this by recruiting one or two new practices through which we will send invitation letters to all participants who have been invited to the NHS DPP (Appendix 10). The invitation letter will be targeted at people who have declined participation in the NHS DPP despite being referred to it by their GP practice. The envelope will also contain an expression of interest form (Appendix 11) with a prepaid envelope.

Participants who have expressed interest in the research will be invited to undertake a 30 minute telephone interview with the chief investigator. The interview will be semi-structured and will be facilitated by a topic guide (Appendix 8). We will seek to undertake up to 5 additional interviews with non-engagers at each phase of the research where underrepresentation becomes apparent.

4.0 Ethical considerations

Overall risks in this study are relatively low. We will obtain fully informed consent from the participants, giving them 2 weeks to read the participant information sheet before deciding to participate. Information in the participant information sheet particularly the voluntary nature of the research, confidentiality, anonymity and their right to withdraw from the study will be reiterated before asking them to sign the consent form. Interview participants will be free to withdraw at any point of the study and data collected up to the point of leaving will only be included in the analysis with their consent. Focus group participants will also be free to withdraw at any point of the study but data collected up to the point of leaving will not be withdrawn from the analysis. Where participants reveal illegal information or unacceptable behaviors, the interview of focus group will be drawn to a close and steps to ensure the researchers safety (below) will be carried out. In the event that a participant is distressed about their condition due to the interview the researcher will refer them to their GP or community pharmacist. The chief investigator (TK) has undertaken a Good Clinical Practice training in 2015 as part of an MSc in clinical research degree. This will ensure that the researcher is competent to perform the tasks of this research and is also qualified by education, training and experience.

4.1 Researcher safety

The research poses a low risk for the researcher's safety since face to face interviews will only be conducted at the University or via telephone and focus groups will be conducted by two members of the research team. The researcher has attended a personal and professional development course at UEA on Researchers Personal Safety. This session offered practical advice about possible hazards that need consideration including minor annoyances that can escalate into verbal and physical confrontations, and techniques to de-escalate or ideally avoid such situations. The session covered safe working strategies that will be implemented by the research team to ensure researchers safety.

Face-to-face interview appointments and focus groups will be scheduled during daylight hours when possible. If an interview appointment is delayed for any reason a member of the research team will be notified and if at any point the researcher becomes uncomfortable actions will be taken to conclude the interview and leave immediately. The researcher will notify a member of the supervisory team when an interview has completed. Arrangements will be made to contact the researcher if they have not heard from them following a certain period.

4.2 Storage of data

Data from the study will be processed as per UEA data management policy [64]. All audio files will be downloaded onto a password protected computer and filed under participant reference before being removed from the digital recorder. Audio recordings will be password protected and stored at UEA on a password protected computer for 3 years or when the PhD thesis is complete. This is to enable the researcher to check the recordings whilst the reports are being written. Transcripts will be anonymized and stored on a secure password protected computer.

Paper files from the questionnaire and the consent forms will be kept in a secured locked filing cabinet in an office at UEA. Data obtained will be solely used for the purposes of this study and will not be processed in a manner incompatible with this. Data will be adequate, relevant and not excessive. All personal data will be kept until the end of the PhD period and research data will be kept for 10 years as per UEA policy.

4.3 Confidentiality

All data will be dealt with to ensure confidentiality and anonymity. Identification of participants will be anonymous with the researchers not seeing any patient identifiable data until participants have expressed an interest to participate in further research. Questionnaires will be anonymous unless the participant expresses interest to be involved in further research. Data recorded during the interviews will only be listened to by the researcher and members of the supervisory team. Transcripts will have all personal and identifiable data removed and will only be analyzed by members of the research team. When reporting the results, any quotes used will be anonymous and will be assigned a reference number e.g. I-01 or FG-01.

4.4 Incentives and reimbursement

Participants will be given a £10 voucher as a thank you for participation and will be reimbursed for transportation. Participating GP practices will also be reimbursed £50 (as calculated via the NIHR primary care resource template) or at the going rate as will be advised by the local CRN team for mailing out questionnaires.

5.0 Dissemination

The findings in this study will be disseminated to healthcare professionals particularly pharmacists at relevant conferences e.g. HSRPP UK. The findings will also be communicated locally through the Norfolk and Norwich CCG, in particular with the team who are involved in delivering the NHS DPP. Nationally we will communicate the findings to the programme director of the NHS DPP who has expressed interest in our study focus. We also hope to publish the findings of this research in a peer reviewed journal.

6.0 Timescale

This study is being conducted as part of a PhD which commenced in June 2016. The research will be conducted up till the end of the PhD period which is July 2019 from protocol write-up to dissemination.

Timescales and work plan

First project: qualitative research	**2017**								**2018/19**		
Activity details	**Mar- May**	**Jun**	**July**	**Aug**	**Sept**	**Oct**	**Nov**	**Dec**	**Jan-Apr**	**May-Oct**	**Oct-Jul 19**
Protocol write-up											
Engagement with stakeholders											
Ethics submission											
Training (conducting interviews and focus groups)											
Questionnaire mailing/texting											
Interviews/focus groups											
Data analysis											
Report writing											
Dissemination of results											

References

1. World Health Organisation, *Global status report on noncommunicable diseases*. 2014: Geneva, Switzerland.
2. Organisation, W.H., *Global status report on non communicable diseases.* 2014: Geneva, Switzerland.
3. International Diabetes Federation, *Diabetes Atlas*. 2006, Brussels.
4. Public Health England, *Diabetes prevalence model*. 2016, Public Health England: London.
5. Hex, N., et al., *Estimating the current and future costs of Type 1 and Type 2 diabetes in the UK, including direct health costs and indirect societal and productivity costs.* Diabet Med, 2012. **29**(7): p. 855-62.
6. National Cardiovascular Intelligence Network (NCVIN). *NHS Diabetes Prevention Programme (NHS DPP) Non-diabetic hyperglycaemia.* 2015 2018-10-22]; Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/456149/Non_diabetic_hyperglycaemia.pdf.
7. NICE, *Type 2 diabetes: prevention in people at high risk. Public health guideline*, N.I.f.H.a.C. Excellence, Editor. 2012.
8. Health and Social Care Information Centre, *Statistics on Obesity, Physical Activity and Diet – England, 2016* 2016, Health and Social Care Information Centre: Leeds.
9. Forouzanfar, M.H.A., L. Anderson, H. R. Bachman, V. F. et. al., *Global, regional, and national comparative risk assessment of 79 behavioural, environmental and occupational, and metabolic risks or clusters of risks in 188 countries, 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013.* Lancet, 2015. **386**(10010): p. 2287-323.
10. Diabetes UK. *Position Statement. Prevention of type 2 diabetes: whole-society interventions to reduce obesity*. 2015; Available from: https://www.diabetes.org.uk/Documents/Position%20Statement%20-%20Prevention%20of%20Type%202%20diabetes;%20whole-society%20interventions%20to%20reduce%20obesity.pdf.
11. World Health Organisation, *Global status report on noncommunicable diseases*. 2014, World Health Organisation Geneva, Switzerland.
12. Association, F.D., *Programme for the prevention of type 2 diabetes in Finland 2003-2010*, H.E. Etu-Seppälä L. Ilanne-Parikka P., Marttila J., Korkee S., Sampo T. , Editor. 2003: Finland.
13. Stolk, R.P., *Screening for diabetes.* BMJ, 2007. **335**(7618): p. 457-458.
14. Ashra, N.B.S., R.; Carter, P.; Davies, M. J.; Dunkley, A. et.el. , *A systematic review and meta-analysis assessing the effectiveness of pragmatic lifestyle interventions for the prevention of type 2 diabetes mellitus in routine practice.* 2015.
15. Orozco, L.J., et al., *Exercise or exercise and diet for preventing type 2 diabetes mellitus.* Cochrane Database Syst Rev, 2008(3): p. CD003054.
16. Nuzhat B Ashra, R.S., Patrice Carter, Melanie J Davies et al, *A systematic review and meta-analysis assessing the effectiveness of pragmatic lifestyle interventions for the prevention of type 2 diabetes mellitus in routine practice.* 2015.
17. Li, G., et al., *The long-term effect of lifestyle interventions to prevent diabetes in the China Da Qing diabetes prevention study: a 20-year follow-up study.* Lancet, 2008. **371**.
18. Ramachandran, A., et al., *The Indian Diabetes Prevention Programme shows that lifestyle modification and metformin prevent type 2 diabetes in Asian Indian subjects with impaired glucose tolerance (IDPP-1).* Diabetologia, 2006. **49**(2): p. 289-297.

19. Knowler, W.C., et al., *Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin.* N Engl J Med, 2002. **346**.
20. Lindstrom, J., et al., *The Finnish Diabetes Prevention Study (DPS): Lifestyle intervention and 3-year results on diet and physical activity.* Diabetes Care, 2003. **26**.
21. Ali, M.K., J. Echouffo-Tcheugui, and D.F. Williamson, *How effective were lifestyle interventions in real-world settings that were modeled on the diabetes prevention program?* Health affairs, 2012. **31**.
22. Dunkley, A.J., D.H. Bodicoat, and C.J. Greaves, *Diabetes prevention in the real world: effectiveness of pragmatic lifestyle interventions for the prevention of type 2 diabetes and of the impact of adherence to guideline recommendations: a systematic review and meta-analysis.* Diabetes Care, 2014. **37**.
23. Gillies, C.L., K.R. Abrams, and P.C. Lambert, *Pharmacological and lifestyle interventions to prevent or delay Type 2 diabetes in people with impaired glucose tolerance : systematic review and meta –analysis.* Br Med J, 2007. **334**.
24. Taylor, J., et al., *Identifying risk and preventing progression to type 2 diabetes in vulnerable and disadvantaged adults: a pragmatic review.* Diabetic medicine : a journal of the British Diabetic Association, 2013. **30**.
25. Orozco, L.J., et al., *Exercise or exercise and diet for preventing type 2 diabetes mellitus*. 2008.
26. Yamaoka, K. and T. Tango, *Efficacy of lifestyle education to prevent type 2 diabetes: a meta-analysis of randomized controlled trials.* Diabetes care, 2005. **28**.
27. Yates, T., et al., *The role of physical activity in the management of impaired glucose tolerance: a systematic review.* Diabetologia, 2007. **50**(6): p. 1116-26.
28. Barry, E., et al., *Efficacy and effectiveness of screen and treat policies in prevention of type 2 diabetes: systematic review and meta-analysis of screening tests and interventions.* BMJ, 2017. **356**.
29. Gillett, M., et al., *Non-pharmacological interventions to reduce the risk of diabetes in people with impaired glucose regulation: a systematic review and economic evaluation.* Health technology assessment, 2012. **16**.
30. Aziz, Z., et al., *A systematic review of real-world diabetes prevention programs: learnings from the last 15 years.* Implementation Science, 2015. **10**(1): p. 172.
31. Whittemore, R., *A systematic review of the translational research on the Diabetes Prevention Program.* Translational behavioral medicine, 2011. **1**(3): p. 480-491.
32. Public Health England, *Consolidating and developing the evidence base and research for community pharmacy's contribution to publuc health: a progress report from Task Group 3 of the Pharmacy and Public Health Forum*. 2014, Public Health England London.
33. Twigg, M.J., et al., *Community pharmacy type 2 diabetes risk assessment: demographics and risk results.* Int J Pharm Pract, 2015. **23**(1): p. 80-2.
34. Corlett, S.A. and J. Krska, *Evaluation of NHS Health Checks provided by community pharmacies.* J Public Health (Oxf), 2015.
35. local Government Association, *Community pharmacy. Local government's new public health role.* . 2013, Local Government Association: London.
36. NHS England, *Improving health and patient care through community pharmacy - a call to action*. 2013.
37. Laws, R.A., et al., *Factors influencing participation in a vascular disease prevention lifestyle program among participants in a cluster randomized trial.* BMC Health Serv Res, 2013. **13**: p. 201.

38. Kullgren, J.T., et al., *Mixed methods study of engagement in behaviors to prevent type 2 diabetes among employees with pre-diabetes.* BMJ Open Diabetes Research & Care, 2016. **4**(1).
39. Penn, L., S.M. Moffatt, and M. White, *Participants' perspective on maintaining behaviour change: a qualitative study within the European Diabetes Prevention Study.* BMC Public Health, 2008. **8**(1): p. 235.
40. Anderson, C., *Health promotion in community pharmacy: the UK situation.* Patient Educ Couns, 2000. **39**(2-3): p. 285-91.
41. Todd, A., et al., *Access all areas? An area-level analysis of accessibility to general practice and community pharmacy services in England by urbanity and social deprivation.* BMJ Open, 2015. **5**(5).
42. Todd, A., et al., *The positive pharmacy care law: an area-level analysis of the relationship between community pharmacy distribution, urbanity and social deprivation in England.* BMJ Open, 2014. **4**(8).
43. Dasgupta, K., et al., *Strategies to Optimize Participation in Diabetes Prevention Programs following Gestational Diabetes: A Focus Group Study.* Plos One, 2013. **8**(7).
44. Morrison, Z., et al., *Understanding experiences of participating in a weight loss lifestyle intervention trial: a qualitative evaluation of South Asians at high risk of diabetes.* BMJ Open, 2014. **4**(6).
45. Gatineau Mary, H.C., Holman Naomi, Outhwaite Helen, Oldridge Lorraine, Christie Anna and Ells Louisa, *Adult obesity and type 2 diabetes*, P. Health, Editor. 2014, Public Health England London.
46. Sargeant, L.A., et al., *Who attends a UK diabetes screening programme? Findings from the ADDITION-Cambridge study.* Diabet Med, 2010. **27**(9): p. 995-1003.
47. DiMaria, L.A., *Understanding the barriers and facilitators of lifestyle intervention programs for preventing diabetes in high risk hispanic adults*, in *Nursing*. 2015, University of Rhode Island USA.
48. Mayega, R.W., et al., *'Change means sacrificing a good life': perceptions about severity of type 2 diabetes and preventive lifestyles among people afflicted or at high risk of type 2 diabetes in Iganga Uganda.* BMC Public Health, 2014. **14**: p. 864.
49. Grace, C., et al., *Prevention of type 2 diabetes in British Bangladeshis: qualitative study of community, religious, and professional perspectives.* BMJ, 2008. **337**.
50. Pharmacy Services Negotiating Committee. *Pharmacy. The heart of our community*. [cited 2016 19th of October]; Available from: http://psnc.org.uk/psncs-work/about-community-pharmacy/.
51. NHS England. *Healthier You: NHS Diabetes Prevention Programme* 2017; Available from: http://www.healthcheck.nhs.uk/commissioners_and_providers/delivery/healthier_you_nhs_diabetes_prevention_programme/.
52. *Questionnaires and Interviews*. Available from: https://www.york.cuny.edu/wac/for-students/handouts-for-specific-courses-and-disciplines/sociology/Questionnaires%20and%20Interviews.pdf.
53. NHS National Patient Safety Agency, *Information Sheets and Concent Forms. Guidance for researchers and reviewrs.* 2009.
54. Medical Research Council, H.R.A., *Consent and Participant Infromation Sheet Preparation Guidance* 2017.
55. Jane Ritchie and Jane Lewis, *Qualitative research practice : a guide for social science students and researchers*, ed. J.R.a.J. Lewis. 2003, London: SAGE Publications LTD.

56. McMillan, S.S., M. King, and M.P. Tully, *How to use the nominal group and Delphi techniques.* International Journal of Clinical Pharmacy, 2016. **38**: p. 655-662.
57. Allen J., Dyas J, and J. M., *Building consensus in health care: a guide to using the nominal group technique.* British journal of community nursing, 2004. **9**(3): p. 110-114.
58. Craig, P., et al., *Developing and evaluating complex interventions: the new Medical Research Council guidance.* BMJ, 2008. **337**.
59. Michie S., A.L., West R. , *The Behaviour Change Wheel: A Guide to Designing Interventions* 1st ed. 2014, London: Silverback.
60. Blaxter, L.H., C & Tight, M. , *How to Research: Data Collection (Chapt 6)*. 1996, Great Britain: Open University Press.
61. Nicola Brace, *Investigating Methods: Collecting, Interpreting and Reporting Evidence in Psychology*, ed. J.M.a.N. Brace. 2014: Open University.
62. Virginia Braun and Victoria Clarke, *Using thematic analysis in psychology.* Qualitative Research in Psychology, 2006. **3**: p. 77-101.
63. Delbecq AL, van de Ven AH, and Gustafson DH, *Group techniques for program planning, a guide to nominal group and Delphi processes*. 1975, Glenview, IL: Foreman and Company
64. University of East Anglia, *UEA Research Data Management Policy.*

Appendix 3.2

Initial ethics approval for the mixed methods study (Chapter 3) and nominal group technique study (Chapter 6)

Appendix 3.2: Initial ethics approval for the mixed methods study (Chapter 3) and nominal group technique study (Chapter 6)

NHS
Health Research Authority

Miss Thando Katangwe
School of Pharmacy
University of East Anglia
Norwich Research Park, Norwich
NR4 7TJ

E-mail: hra.approval@nhs.net

13 September 2017

Dear Miss Katangwe

Letter of HRA Approval

Study title:	**The community pharmacy setting for the delivery of diabetes prevention programmes: a mixed methods study in people with 'prediabetes'**
IRAS project ID:	**227930**
Protocol number:	**TK-MT-Rev2**
REC reference:	**17/EM/0314**
Sponsor	**University of East Anglia**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating

organisations to opt out of the study, or request additional time, before their participation is assumed.

- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators"*, issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and e-mailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

Your IRAS project ID is **227930**. Please quote this on all correspondence.

Yours sincerely

Rekha Keshvara
Senior Assessor

E-mail: hra.approval@nhs.net

Copy to: *Mr Samuel Hills, University of East Anglia (Sponsor contact)*
Claire Symms, South Norfolk CCG (R&D contact)

Appendix 3.3

Ethics amendments approvals for the mixed methods study (Chapter 3) and nominal group technique study (Chapter 6)

Appendix 3.3: HRA approval for amendment number one

Amendment Categorisation and Implementation Information

Dear Miss Katangwe,

Thank you for submitting an amendment to your project.

If you have participating NHS/HSC organisations in any other UK nations we will forward the information to the relevant national coordinating function(s). Please note that you may only implement changes described in the amendment notice.

What Happens Next?

Information Specific to Participating NHS Organisations in England

1. You should now share details of the amendment and, if applicable, amended documents, together with this e-mail, with all participating NHS organisations in England. In doing so, you should include the NHS R&D Office, LCRN (where applicable) as well as the local research team. A template e-mail to notify participating NHS organisations in England is provided on the HRA website.
2. The participating NHS organisations in England should prepare to implement this amendment.
3. Your amendment has been assessed against HRA standards. **This e-mail also constitutes HRA Approval for the amendment, and you should not expect anything further from the HRA.**
4. You may implement your amendment at all participating NHS organisations in England 35 calendar days from the day on which you provide the organisations with this e-mail and your amended documents (or as soon as the participating NHS organisation confirm that you may implement, if sooner). **NHS organisations do not have to confirm they are happy with the amendment.**
5. You may not implement the amendment at any participating NHS organisations in England that requests additional time to assess, until it confirms that it has concluded its assessment.
6. You may not implement at any participating NHS organisation in England that declines to implement the amendment.

IRAS Project ID:	227930
Short Study Title:	The role of community pharmacy in diabetes prevention
Date complete amendment submission received:	07 March 2018
Amendment No./ Sponsor Ref:	1
Amendment Date:	01 March 2018
Amendment Type:	Non-substantial

Outcome of HRA Assessment	**This e-mail also constitutes HRA Approval for the amendment,** and you should not expect anything further from the HRA.
Implementation date in NHS organisations in England	35 days from date amendment information together with this e-mail, is supplied to participating organisations
For NHS/HSC R&D Office information	
Amendment Category	**A**

If you have any questions relating to the wider HRA approval process, please direct these to hra.approval@nhs.net.

If you have any questions relating to this amendment in one of the devolved administrations, please direct these to the relevant national coordinating function.

Additional information on the management of amendments can be found in the IRAS guidance.

Please do not hesitate to contact me if you require further information.

Kind regards

Jemima Clarke

Health Research Authority

Ground Floor | Skipton House | 80 London Road | London | SE1 6LH

E.hra.amendments@nhs.net

W. www.hra.nhs.uk

Appendix 3.3 HRA approval for amendment number two

Dear Miss Katangwe,

IRAS Project ID:	227930
Short Study Title:	The role of community pharmacy in diabetes prevention
Amendment No./Sponsor Ref:	2
Amendment Date:	15 December 2018
Amendment Type:	Substantial Non-CTIMP

I am pleased to confirm **HRA and HCRW Approval** for the above referenced amendment.

You should implement this amendment at NHS organisations in England and Wales, in line with the conditions outlined in your categorisation e-mail.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/.

Please contact hra.amendments@nhs.net for any queries relating to the assessment of this amendment.

Kind regards,

Natalie

Natalie Wilson

Assessor

Health Research Authority

HRA | NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle-upon-Tyne | NE2 4NQ

Appendix 3.4

Research and Development (R&D) office approvals for the mixed methods study (Chapter 3) and nominal group technique study (Chapter 6)

Appendix 3.4: R &D Initial study approval

Dear Sponsor/CI/Coordinator

Full Study Title: 2017GP29 (227930) Community pharmacy in diabetes prevention.

This e-mail confirms that the following arrangements are in place to support the study:

- HRA Approval is in place
- Agreements are drafted and acceptable.
    - SOAs will be used as agreement with Practices
- Human Resources arrangements (letter of access) are not required.

Practice/Practices will need to confirm their capacity and capability to deliver the research by returning:

- **E-mail confirmation of SOA, or signed SOA, signed RISP or Sponsor site signed agreement.**

Please note this e-mail is confirmation of arrangements to support the study within Norfolk, if you wish to open the study in other areas within CRN: Eastern please do get in touch.

Please can you advise us of the following:

- Practice /practices that agree to participate
- Amendments to the study and revised paperwork which could affect how the study runs locally.
- Completion date for study locally.

Once your study has completed, we would be grateful if you could forward a copy of the final report, a one page lay summary and any publications associated with the study to snccg.randdoffice@nhs.net .

May we take this opportunity to wish you well with your research and we look forward to hearing the outcomes for the study. Please note the reference number for this study is **Ref: IRAS 227930** and this should be quoted on all correspondence.

Kind regards

Clare Symms
Norfolk and Suffolk Research Office
Research Management and Finance Lead

Appendix 3.4: R &D Approval for amendment number one

Dear Thando

Re: Arrangements to support the below amendment in Norfolk Pharmacies, Norfolk GP Practices and Norfolk CCGs (North Norfolk, Norwich and South Norfolk)

Full Study Title: 2017GP40 (IRAS 233631) The community pharmacy setting for the delivery of diabetes prevention programmes: views and perceptions of stakeholders

Type	Title	Date of Amendment	Date of HRA Approval	Summary of Amendment
Non substantial	Amendment 1	14/02/18	25/02/18	Increase in number of participants for each project phase; inclusion of local authority, clinical networks, NHS England and Public Health England; revision of timeline of study to 18 months.

We acknowledge receipt of this amendment for which **regulatory and HRA approvals are in place** and are happy for it to be implemented in **Norfolk pharmacies, GP practices and CCGs.**

It is a sponsor responsibility to communicate the changes to sites as per the HRA e-mail dated 25/02/18.

Kind regards

Clare Symms
Norfolk and Suffolk Office
Research Management and Finance Lead

Appendix 3.4: R &D Approval for amendment number two

Dear Thando

Arrangements to support the below amendments in Norfolk GP Practices

Full Study Titles: 2017GP29 (227930) Community pharmacy in diabetes prevention

Study	Type	Title	Date of Amendment	Date of HRA Approval	Summary of Amendment
2017GP29 (IRAS 227930) Community pharmacy in diabetes prevention	Substantial	2	15/12/18	03/01/19	End date of study has been revised to 31/07/19. Change in academic supervisor. Change in sponsor contact. Amendment to data collection methods. Protocol updated to reflect changes. A new topic guide has been developed.

We acknowledge receipt of these amendments for which **regulatory and HRA approvals are in place** and are happy for these to be implemented in **Practices.** It is a sponsor responsibility to communicate the changes to sites as per the HRA e-mails dated 19/12/18 and 03/01/19.

Kind regards

Clare Symms

Norfolk and Suffolk Office

Research Management and Finance Lead

Appendix 3.5

Questionnaire covering letter

Appendix 3.5: Questionnaire covering letter

University of East Anglia

The community pharmacy setting for the delivery of diabetes prevention programmes: a mixed methods study in people with 'prediabetes'

Invitation to participate in research

The University of East Anglia (UEA) is currently working on a project to design a Diabetes Prevention Program that could be delivered in the community pharmacy. We would like to invite you to participate in our research study by filling in a questionnaire. Before you decide to participate, please read the information below to help you understand what this research is about, why it is being conducted and what it would involve for you. We suggest this should take no more than 10 minutes.

What is the purpose of the study?

The aim of the research is to gather information and general views about how the community pharmacy could help in preventing type 2 diabetes. We would like to gather this information from people who are at a high risk of developing type 2 diabetes, who have been referred onto the NHS Healthier You programme. This information will then assist in the design of a community pharmacy based diabetes prevention programme.

Why have I been approached?

Your local medical practice has identified you as eligible for this study since you have been referred to the NHS Healthier You programme. If you are still waiting to be contacted for your first appointment to the programme, your views will still be valuable for this research. This questionnaire has been posted via your medical practice and therefore the research team at UEA have had no access to your medical notes and will not know that you have received this letter and questionnaire.

What will happen if I agree to participate? If you decide to take part we would like you to fill in a questionnaire that will take approximately 15 minutes. Please read the information at the top of the questionnaire, fill it in and return it to UEA in the prepaid envelope or click submit (electronic option). At the end of the questionnaire, we would also like you to

indicate whether you would like to be involved in further research involving a telephone or face to face interview or a group discussion. If you decide to participate in further research, we will reimburse any transportation costs you may incur and we will give you a £10 voucher as a thank you.

Do I have to participate?

Participation is entirely voluntary. You are under no obligation to fill in the questionnaire or participate in further research. Please be assured that if you decide not to participate this will in no way affect the care you receive from your GP or the NHS Healthier You programme.

What are the possible disadvantages and risks of taking part?

We do not foresee any potential risks of being part of this study. If you decide to participate, the only burden will be the time it will take to fill in the questionnaire or the time it will take to be interviewed or be involved in group discussions (for those who volunteer for further research).

What are the possible benefits of taking part?

There are no immediate benefits for participating, apart from taking part in research that may aid the improvement of services available for people at high risk of developing type 2 diabetes.

Will my taking part in the study be kept confidential?

Any personal data that we may collect from you will be kept confidential and reported anonymously. Personal data will be destroyed after 3 years and questionnaire responses will be stored securely at UEA for up to 10 years in line with the Data Protection policy. The research team at UEA have had no access to your medical notes and will not know that you have received this letter and questionnaire.

What will happen to the results of this survey?

This work is being conducted as part of a PhD research project and therefore we intend to report the findings in a thesis and publish the findings in a peer reviewed journal. Any published information will be reported anonymously.

Who is organising and funding this research?

This work is being conducted as part of a PhD research project undertaken by Thando Katangwe, a community pharmacist. The research is being carried out under the supervision of Dr Michael Twigg, a lecturer in pharmacy practice at UEA. The research is being funded by the University of East Anglia, The Harold and Marjorie Moss Charitable Trust Fund and Boots UK.

Who has reviewed the study? All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and approved by the NHS Health Research Authority (IRAS Project ID: 227930).

What if there is a problem?

If you have any questions at any point please feel free to contact Thando Katangwe (E-mail: T.Katangwe@uea.ac.uk; Tel: 01603591973) or (Dr Michael Twigg (E-mail: M.Twigg@uea.ac.uk; Tel: 01603592015).

Thank you for taking time to read about the research,

Yours Sincerely,

Thando Katangwe, principal investigator

Miss Thando Katangwe
Research Pharmacist, School of Pharmacy
University of East Anglia, Norwich, NR4 7TJ
Tel: 01603591173

Appendix 3.6

Questionnaire for the mixed methods study

Appendix 3.6: Questionnaire

University of East Anglia

The community pharmacy setting for the delivery of diabetes prevention programmes: a mixed methods study in people with 'prediabetes'

Thando Katangwe, PhD Student, UEA.

There are 4 parts within this questionnaire:

1. Information about you
2. Feedback on the NHS Healthier YOU Diabetes Prevention Programme
3. Information about your health and community pharmacy
4. Expression of interest in further research

Please read the instructions at the beginning of each section and fill in the sections that are relevant to you. If you make a mistake don't worry, just cross it out and select the correct answer (or just reselect the correct answer – electronic option). This questionnaire should take no longer than 15 minutes to complete and there are no right or wrong answers. You are under no obligation to fill in this questionnaire and if you choose not to, please be assured that this will in no way affect the care you receive from your GP or the programme.

Thank you for taking the time to complete the questionnaire,

Yours Sincerely,

Thando Katangwe

Reference number: | | | | | | |

Part 1: about YOU. For question 1 please write your age in the box provided and for question 2, 3 and 4 please tick ✓ the answer that best describes you.

1 What is your age?

Please write your age in years in the box

2 What is your gender?

Male ☐ Female ☐ Prefer not to say ☐

3 What is your ethnic group?

White ☐ Mixed ☐ Black ☐ Chinese ☐ Asian ☐ Other ☐

4 **Employment: are you currently?**

Employed ☐ Student ☐ Retired ☐ Unemployed ☐

Part 2: about the NHS Healthier YOU Diabetes Prevention Programme

Please tick ✓ the answer that best describes you and your views about the NHS Diabetes Prevention Programme.

5 What is your current involvement in the 'NHS Healthier You Programme'?

Waiting for an initial assessment	☐	Attending but not completed	☐	Attended some sessions but stopped going	☐	Completed	☐	Declined/not really interested	☐

Please go to Section A if you have attended some sessions

Please go to Section B if you haven't attended any sessions

Section A

		Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
6	The location of the programme was convenient for me	☐	☐	☐	☐	☐
7	The times that the sessions were offered were convenient for me	☐	☐	☐	☐	☐
8	I found attending the sessions as a group helpful	☐	☐	☐	☐	☐

9	The programme has helped me or is helping me to lose weight	☐	☐	☐	☐	☐
10	The programme has helped me or is helping me to exercise more	☐	☐	☐	☐	☐
11	Please indicate your overall satisfaction level with the programme	Strongly Dissatisfied ☐	Dissatisfied ☐	Neutral ☐	Satisfied ☐	Strongly satisfied ☐
12	Please write  any other comments in the box provided					
	Section B	**Strongly disagree**	**Disagree**	**Neither agree nor disagree**	**Agree**	**Strongly agree**
13	The location of the programme is not convenient for me	☐	☐	☐	☐	☐
14	The times that the sessions are offered are not convenient for me	☐	☐	☐	☐	☐
15	I don't feel that I need the programme	☐	☐	☐	☐	☐

16	Please write  any other reasons for not attending in the box provided	

Part 3: about YOUR health and community pharmacy

Please tick ✓ the answer that best describes you and write your comments in the box provided.

17 Do you take any prescribed medication?

Yes

☐ please go to question 18

No

☐ please go to question 20

18 Who dispenses your medication?

Community pharmacy ☐

Dispensing doctors ☐

19 How do you collect your prescribed medication from the pharmacy?

In person ☐

Someone else collects ☐

Pharmacy delivery service ☐

20 How often do you visit your local community pharmacy?

Most days ☐

About once a month ☐

Once every 2 to 3 months ☐

2 or 3 times a year ☐

Never ☐

21 Approximately how far do you have to travel to your local community pharmacy?

1 mile ☐

2 miles ☐

3-4 miles ☐

+5 miles ☐

Don't know ☐

22 Which community pharmacy service have you used before?

NHS Health Check ☐

Weight loss programme ☐

Smoking Cessation ☐

Diabetes Check ☐

Cholestrol check ☐

	Blood pressure check ☐	Health leaflets ☐	Over the counter advice ☐	Other ☐	None /never heard of these ☐					
			Strongly disagree	**Disagree**	**Neither agree nor disagree**	**Agree**	**Strongly agree**			
23	**I think the community pharmacy is capable of providing a diabetes prevention service**		☐	☐	☐	☐	☐			
24	**I would consider using the community pharmacy for a diabetes prevention service**		☐	☐	☐	☐	☐			
25	**I would be motivated to attend a prediabetes screening or prevention service provided by the community pharmacy team**		☐	☐	☐	☐	☐			
26	**What are your thoughts on the community pharmacy providing prediabetes screening and prevention services?** Please write your comments in the box provided.									

Part 4: expression of interest to participate in further research Please **ONLY** fill in this section if you would like to participate in an interview or focus group discussion. Please note that filling in this form doesn't mean that you are committing to participate. The researcher will send you further information to help you decide if you would like to participate. Please write  the information in the boxes provided and tick ✓ your preferred method of research.	
Name	
Preferred contact number	
E-mail address	
Address	
Which would you prefer	Telephone interview ☐
	Face to face interview ☐
	Group discussion ☐

Thank you ***for taking the time to complete this questionnaire!***

Please return your completed survey in the free post envelope provided (or click submit when finished).

Appendix 3.7

Interview and focus group cover letter

Appendix 3.7: Interview and focus group cover letter

University of East Anglia

The community pharmacy setting for the delivery of diabetes prevention programmes: a mixed methods study in people with 'prediabetes'

The University of East Anglia (UEA) is currently working on a project to design a Diabetes Prevention Program that could be delivered in the community pharmacy. As part of the project we would like to gather general views about the role of the community pharmacy in the prevention of diabetes. This project forms part of a PhD being undertaken by the lead researcher.

As part of this project we would like to learn about factors that influence people to take part in diabetes prevention programs and to gain their views on the delivery of a community pharmacy based program. We would like to invite you to participate in an interview that will take approximately 1 hour or a group discussion that will take approximately 1.5 hours. If you participate in the interview or group discussion, reasonable travel costs will be reimbursed together with a £10 voucher as a thank you.

Please read the participant information sheet and if you have any questions at any point please feel free to contact Thando Katangwe by e-mail (T.Katangwe@uea.ac.uk) or by telephone (01603 591973).
Thank you in anticipation for your help.
Yours Sincerely,

Miss Thando Katangwe
Research Pharmacist, School of Pharmacy
University of East Anglia, Norwich, NR4 7TJ
Tel: 01603591173

Appendix 3.8

Participant Information Sheet

Appendix 3.8: Participant Information Sheet

University of East Anglia

The community pharmacy setting for the delivery of diabetes prevention programmes: a mixed methods study in people with 'prediabetes'

We would like to invite you to take part in our research study. This information sheet is designed to help you understand this project and what it will involve. It is set out as a series of questions and answers. Please take time to read the following information carefully and if you wish to discuss it with us, please do not hesitate to contact us (T.Katangwe@uea.ac.uk). We suggest this should take no more than 15 minutes. This research is being conducted as part of a PhD by the Principal Investigator, Thando Katangwe.

What is the purpose of the study?

The purpose of this study is to understand what influences participation in Diabetes Prevention Programmes. We would also like to obtain views and perspectives that may help to design a community pharmacy based programme.

Do I have to take part?

Taking part is entirely voluntary. The researchers will allow a minimum of two weeks after sending you this information sheet before contacting you to ask if you are still interested. If you do not wish to participate please inform us and you will receive no further correspondence from us.

What are the possible benefits of taking part?

The results of this project could be used to improve services that are provided for people at high risk of developing type 2 diabetes. The findings may also help the development of diabetes prevention services provided in the community pharmacy.

What will I have to do?

If you decide to participate in this study you will be given an option to participate in a telephone interview or face to face interview or group discussion. Interviews will be conducted with the Principal Investigator (TK) and will last approximately 30 – 60 minutes. Group discussions will last approximately 60 – 90 minutes and will be managed by the Principal Investigator and another member of the research team (MT). The interviews and group discussions will be audio recorded and will involve three main topics:

What are your views and experiences of being at high risk of type 2 diabetes?
What influenced your decision to engage or not to engage in Diabetes Prevention Programme?
What role can the community pharmacy play in diabetes prevention?

What happens next?
If you decide to take part the researcher will contact you after 2 weeks of receiving this information sheet to arrange a time and location that is most convenient for you.

Will my taking part in the study be kept confidential?
Yes. All your personal information will be kept strictly confidential in accordance with the Data Protection Act 1998. All recorded information provided by you will be kept anonymous and will be reported in such a way that you cannot be identified. All data will be stored in a locked cabinet at the UEA or on a password protected UEA computer. Your personal data will be destroyed after 3 years or at the end of the PhD and all the research data will be kept for 10 years in line with the UEA Data Protection policy.

Will I be able to withdrawal from the study?
You will be free to withdraw from the research at any point without any effect on your care. If you decide to leave in the middle of the interview due to time constraints or any other reason you will also be free to remove your data from analysis – we will ask you if you want us to do this. However, if you feel you need to leave in the middle of the group discussion, we will not be able to remove your data and it will be included in the final analysis.

What will happen to the results of the research study?

The findings of the study will be shared with you. This work is being conducted as part of a PhD research project and therefore we intend to report the findings in a thesis and publish the findings in a peer reviewed journal. Any published information will be reported anonymously.

Will I be compensated or reimbursed for taking part?

The research team will give you a £10 voucher as a thank you for participating in the study. If you have to travel especially for the face-to-face interviews or focus group, you will be reimbursed for any travelling costs. Please inform the research team prior to attendance of the interviews or focus groups.

Are there any disadvantages to take part in the study?

We do not foresee any disadvantages to taking part in the research. However, in the unlikely event that distress is caused by the research process, the lead researcher and supervisor, who are both experienced pharmacists, will provide you with immediate support, information and guidance. If necessary, where you require ongoing support, the research team will refer you to your GP or community pharmacist after obtaining your consent and briefing them about the research to ensure that they are aware of the issues that need to be followed-up.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and approved by the NHS Health Research Authority.

Who is funding this research?

This research is being funded by the University of East Anglia, the Harold and Marjorie Moss Charitable Fund and Boots UK.

What if I have a complaint?

If you have any questions about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [01603 591973]. If you remain unhappy and wish to complain formally, you can do this by contacting the Head of School

of Pharmacy and Chemistry, Professor Mark Searcey via e-mail: m.searcey@uea.ac.uk or telephone 01603 592026.

For further information please contact:

Principal Investigator
Miss Thando Katangwe
School of Pharmacy
University of East Anglia,
Norwich Research Park,
Norwich, NR4 7TJ, Tel: 01603 591973

Research supervisor
Dr Michael Twigg
School of Pharmacy,
University of East Anglia,
Norwich Research Park
Norwich, NR4 7TJ, Tel: 01603 592015

Appendix 3.9

Interview/focus group consent form

Appendix 3.9: Interview/focus group consent form

University of East Anglia

The community pharmacy setting for the delivery of diabetes prevention programmes: a mixed methods study in people with 'prediabetes'

	Please initial box
I confirm that I have read and understand the information sheet dated June 2017 version 1 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
I agree to take part in the above study to explore the factors influencing engagement in diabetes prevention programs	
I am willing to allow the interview or group discussion to be recorded for the purposes of research analysis and possible publication of findings	
I understand that data will be anonymised and will be stored securely at the University of East Anglia	
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. I agree to take part in the above study.	

Name of participant Date Signature

Name of person taking consent Date Signatur

Appendix 3.10

Invitation letter

Appendix 3.10: Invitation letter

University of East Anglia

The NHS Healthier You programme – how can we make it better?

An invitation for you to tell us your opinion by being involved in research

Dear Sir/Madam

I am a PhD student at the University of East Anglia working on a research project to find out whether any changes need to be made to how the NHS supports people who are at risk of getting diabetes.

Why have I been sent this letter?

Your medical practice sent this letter for me because they know that they referred you to the NHS Healthier You programme. I have had no access to your medical notes and will not know that you have received my letter.

What is the purpose of the study?

I want to understand what makes people decide whether or not to get involved with the NHS Healthier You Programme. I'm particularly interested in people who have decided not to enrol on the programme because this will help me find out other ways in which people want the NHS to help them reduce their risk of getting diabetes.

What will happen if I agree to be involved?

If you decide to take part in my research, please fill in the expression of interest form included with this letter and put it in the prepaid envelope. When I get your form, I will telephone or e-mail you to arrange a 30 minute telephone interview. I will record interview so that I don't forget anything that you tell me. We will talk about the following three main things:

What are your views and experiences of being at risk of getting type 2 diabetes?

What were your reasons for not enrolling on to the NHS Healthier You Programme?

Do you think that the community pharmacy team may be able to help in any way in diabetes prevention?

Do I have to take part?

It is completely up to you whether you take part in my research. If you decide that you don't want to be involved it will in no way affect the care that you get from your medical practice team or any other NHS programme.

What are the possible disadvantages and risks of taking part?

I don't think that there are any risks associated with being involved in the study as your involvement is having a telephone conversation with me. In the unlikely situation that something discussed in the telephone call worries you, as an experienced pharmacist, I will provide you with immediate support and information. However, should you need additional support, with your agreement I will refer you to your GP or community pharmacist after briefing them about the research so that they would know how best to support you.

What are the possible benefits of taking part?

Your involvement may help to improve NHS services that are available for people at high risk of developing type 2 diabetes.

Will I be compensated or reimbursed for taking part?

After the interview, I will post a £10 voucher to you as a thank you for your help.

Will my taking part in the study be kept confidential?

Yes. I will keep all of your personal information as confidential in accordance with the Data Protection Act 1998. I will report the interview in such a way that you cannot be identified. Your personal information will be destroyed after 3 years or at the end of my PhD.

What will happen to the results of the research study?

I will put in my PhD thesis information that I find out from the interviews and publish them in a scientific journal. I will never report any information that would allow the people that I interviewed to be identified.

Who is organising and funding this research?

I am organising and carrying out the research project and my background is in community pharmacy. My research is being supervised by Dr Michael Twigg and Dr Debi Bhattacharya,

who are both lecturers and researchers at UEA. My research is being funded by the University of East Anglia, The Harold and Marjorie Moss Charitable Trust Fund and Boots UK.

Who has reviewed the study?

An NHS Research Ethics Committee has looked at this research to protect your safety, rights, wellbeing and dignity. They have confirmed that it is OK for me to do this research.

What if there is a problem?

If you have any questions please feel free to contact me (Miss Thando Katangwe; e-mail: T.Katangwe@uea.ac.uk; Tel: 01603591973) or (Dr Michael Twigg (e-mail: M.Twigg@uea.ac.uk). If you would prefer to speak to someone outside the research team then please feel free to contact Professor Mark Searcey, the Head of Schools of Pharmacy and Chemistry (e-mail: m.searcey@uea.ac.uk; Tel: 01603592026).

Thank you for taking the time to read about my research,

Yours Sincerely,

Thando Katangwe
Research Pharmacist, School of Pharmacy
University of East Anglia, Norwich, NR4 7TJ
Tel: 01603591173

Appendix 3.11

Expression of interest form

Appendix 3.11: Expression of interest form

University of East Anglia

The community pharmacy setting for the delivery of diabetes prevention programmes: a mixed methods study in people with 'pre-diabetes'

Thando Katangwe, PhD Student, UEA.

Expression of interest to participate in a 30-minute telephone interview

Please ONLY fill in this form if you have chosen NOT to enrol onto the NHS Healthier You Diabetes Prevention Programme.

Please note that filling in this form doesn't mean that you are committing to participate. The researcher will contact you and give you the opportunity to ask further questions about the research to help you decide if you would like to participate. Please write  the information in the boxes provided	
Name	
Preferred contact number	
E-mail address	
Address	

Thank you for taking the time to complete the form!

Please return your completed form in the prepaid envelope provided.

Appendix 3.12

Topic guide

Appendix 3.12: Topic guide

University of East Anglia

Topic	Stem questions	Prompts	Probes & notes
Contextual background	Just to start can you tell me a bit about yourself (yourselves)?	work, family, hobbies	Tell me more about that?
	Tell me about your reaction after you received a letter telling you are at high risk of developing type 2 diabetes?	What did this mean to you? What difference has it made to your diet and lifestyle? Did you seek for more information – where did you look?	You mentioned X could you explain a bit more about that?
Engagement barriers and facilitators	What influenced your decision to engage, not engage or leave in the Healthier You DPP?	Capability e.g. knowledge, physical and psychological Opportunity e.g. work, social & family commitments, availability, location and time. Importance of timing and location is in encouraging you to participate in the programme? Motivation e.g. high or low motivation, intentions, choices, habits	Could you give me an example? What do you mean by that?
Community pharmacy	What role can the community pharmacy play in diabetes prevention?	Views about who should be delivering diabetes prevention services?	It's interesting that you

		Who would you like to talk to? (nurses, pharmacists, GPs or other trained individuals) Have you thought about your pharmacists? What is your relationship with your local community pharmacy? Would you be motivated to visit the community pharmacy for help and information? What support do you think the community pharmacy could offer you? Regular visit to community pharmacy? Views about community pharmacy and DPP Screening for pre-diabetes? Would you like them to be involved? Delivering part or all of the diabetes prevention programme? Are they the right people to deliver this service (appropriate skills)? Opportunity to access this kind of service from the community pharmacy? What would you need to access this service?	mentioned……how do you foresee that to be a problem?
Any other comments	Any other comments or feedback about the community pharmacy?		

Appendix 4.1

Protocol for the qualitaive study (Chapter 4) and nominal group technique study (Chapter 6)

Appendix 4.1: Protocol for the qualitative study (Chapter 4) and Nominal group technique study (Chapter 6)

University of East Anglia

The community pharmacy setting for the delivery of diabetes prevention programmes: views and perceptions of stakeholders

Chief investigator

Thando Katangwe (T.Katangwe@uea.ac.uk)

PhD Student, School of Pharmacy, University of East Anglia.

Research supervisors

Dr M. Twigg (M.Twigg@uea.ac.uk)

Lecturer in Pharmacy Practice, School of Pharmacy, University of East Anglia.

Dr J. Sokhi (J.Sokhi@uea.ac.uk)

Lecturer in Pharmacy practice, School of Pharmacy, University of East Anglia.

Dr C. Kirkdale (charlotte.kirkdale@boots.co.uk)

Health Outcomes Research Manager | Pharmacy Contract Framework & Outcomes, Boots UK.

Protocol No.	Revision	Date	Investigator Sig.	Sponsor Sig.
TK-MT-REV3	14/12/2018	14/12/2018	T.K.	MK

1.0 Introduction

Diabetes mellitus is one of the most common non-communicable diseases responsible for the major health and development challenges of the 21st century [1]. It remains one of the leading causes of death in most developed countries and a financial burden to many health economies [1, 2]. In England, 3.8 million people are estimated to be living with the condition, with 90% of all cases attributable to type 2 diabetes [3]. The National Health Service (NHS) in England spends approximately £8.8 billion a year (10% of the total NHS budget) on the management of diabetes and its complications [4] . In addition, five million people in England are estimated to have 'prediabetes', a term used to denote blood glucose levels above normal range but not high enough for diagnosis of type 2 diabetes [5, 6]. Prediabetes is not a clinical entity in itself, but rather denotes an increased risk of developing type 2 diabetes. The risk of developing type 2 diabetes depends on multiple risk factors, of which obesity is most significant [7]. Obesity accounts for approximately 80-85% of the overall risk of developing type 2 diabetes and together with physical inactivity, are estimated to cause the large proportion of the global diabetes burden [8, 9].

Central to the approach for the prevention of type 2 diabetes is the promotion of healthy diet and exercise to reduce the rise in obesity [1, 10, 11]. Evidence suggests that if individuals at high risk are identified before overt diabetes develops and intensive lifestyle interventions are implemented, the onset of type 2 diabetes may be delayed or even prevented [12, 13]. In England, the NHS Diabetes Prevention Programme (DPP) has been developed in view of such evidence [14]. The effectiveness of lifestyle based DPPs was initially demonstrated in several large randomised controlled trials and subsequently by smaller translational studies [15-20]. Translational research has shown pragmatic interventions, delivered across diverse settings and populations to be effective in terms of weight loss [19, 20] and delaying the incidence of type 2 diabetes [21-26]. A sustained lifestyle change has been highlighted as the key to success in DPPs, with greatest benefits observed with highest compliance and achievement of targets (weight loss and diet) [27]**.** However, due to low participation rates attributed to either non-eligibility, refusal to participate or attrition, the population level impact of DPPs has often been criticised [26-28].

Primary care based interventions have been associated with the lowest attrition and highest reach to the targeted populations [6, 28, 29]. The National Institute of Health and Care Excellence (NICE) recommend the delivery of intensive lifestyle programs by primary health care teams which includes community pharmacies [6]. However, most pragmatic studies have been conducted in primary care settings such as GP

practices, with very little research exploring a community pharmacy setting [28, 29]. Over recent years the traditional dispensing role of community pharmacists has developed towards the delivery of public health services such as diabetes screening, smoking cessation and weight reduction programmes [30-34]. This is primarily due to accessibility. Intervention accessibility has been highlighted amongst the barriers of participant engagement in disease prevention programs. Laws *et al*. who explored factors influencing participation in a practice based vascular disease prevention program highlighted accessibility barriers such as transportation and geographical location [35]. In addition, they highlighted challenges in organising group based sessions suitable to most of the participants and identified the need for flexibility including delivering night time, weekend or individual sessions and telephone follow-up [35]. Kullgren *et al*. who examined engagement of people found to have prediabetes following work based screening identified primary reasons for not engaging as work and social commitments and accessibility of exercise facilities [36]. Similar social barriers were also highlighted by Penn *et al.* who aimed to understand the experience of participants who maintained behaviour change following a lifestyle intervention [37].

Intervention barriers such as accessibility, work and social barriers highlighted by qualitative research to date could be addressed by using the community pharmacy setting. The community pharmacy, as the most visited NHS care setting in England, is accessible to approximately 90% of the population within a 20-minute walk [38-40]. The availability of a private consultation room within the majority of the community pharmacies (90%) in England and the long opening hours including weekends, makes them a flexible setting for the delivery of public health services such as the DPP [30, 33]. Additionally, potential facilitators to engagement such as face to face interaction with professionals [37, 41] and continuity of providers [29, 42] are highly applicable to community pharmacy.

In England, the accessibility of community pharmacies increases to over 99% in highly deprived populations including lower socioeconomic groups, males and ethnic minority groups [40]. In these populations, obesity, the greatest modifiable risk factor of type 2 diabetes, has been shown to have the highest prevalence [43, 44]. Research investigating barriers and facilitators to engagement in different ethnic backgrounds such as South Asians [42], Hispanic [45], Black Africans [46] and Bangladeshi [47] has highlighted common barriers as language [42, 45, 47], social roles including faith based responsibilities [42, 47] and poor cultural and religious understanding of healthcare professionals [30, 47, 48]. With evidence showing that DPPs can be successfully delivered by lay personnel [19], pharmacy support staff could play an important role in engaging ethnic minorities and other hard to reach groups as they tend to reflect the culture of the local population.

In summary, qualitative research has highlighted important barriers and facilitators to engagement in DPPs that may be addressed by delivering lifestyle interventions in the community pharmacy setting. However, due to inadequate research exploring the role of this setting in diabetes prevention, there is a need for evidence addressing the acceptability and feasibility of a programme delivered in the community pharmacy. This study aims to characterise the current and potential role of community pharmacy in the prevention of type 2 diabetes and to explore community pharmacy as an option for the delivery of diabetes prevention programmes from the perspective of stakeholders. To date, majority of qualitative research has focused on exploring barriers and facilitators to engagement from the perspective of people at high risk of type 2 diabetes [36, 41, 42, 45]. Very few studies have explored the views of other stakeholders such as GPs, pharmacists, commissioners and those involved in delivering the interventions [35].

The Medical Research Council (MRC) in the UK advocates the use of appropriate theory, supplemented if necessary by new primary research e.g. interviews with 'stakeholders', when developing effective complex interventions [49]. Therefore, this study will use focus groups and interviews underpinned by a behaviour change model (COM-B) proposed by Mitchie *et.al* to explore the views and perceptions of stakeholders that could be involved in the delivery or commissioning of a community pharmacy diabetes prevention programme [50]. The views and perceptions of service users (people at high risk of developing type 2 diabetes) are being explored in a separate study which will run in parallel and together the findings of both studies will be used to shape the final model.

2.0 Aim and Objectives

2.1 Aim

To explore the community pharmacy setting as an option for the delivery of Diabetes Prevention Programmes by eliciting views and perceptions of stakeholders in Norwich and Norfolk.

2.2 Objectives

1 To characterise the current and potential role of community pharmacy in the prevention of type 2 diabetes from the perspective of stakeholders.
2 To describe the barriers and facilitators of delivering a diabetes prevention programme in the community pharmacy setting form the perspective of stakeholders
3 To explore the implementation and acceptability of a model for a community pharmacy based DPP with stakeholders.

3.0 Methodology

Ethics and governance approval will be obtained from the Health Research Authority and the Faculty of Medicine and Health Sciences Research Ethics committee at the University of East Anglia before commencing the research.

Community pharmacy structure:

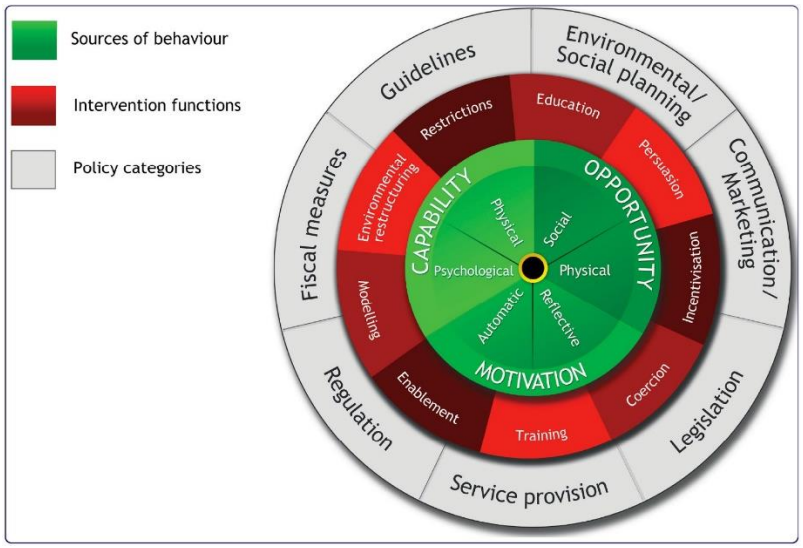
In England, all community pharmacies provide healthy living advice to patients as part of the public health element of the Community Pharmacy Contractual Framework (CPCF) [51]. Community pharmacies also provide at least one locally commissioned public health service e.g. smoking cessation or NHS Health Checks. Public health services provided by community pharmacies are commissioned in line with local need identified by local authorities and can be contracted by different commissioners, including local authorities, Clinical Commissioning Groups (CCGs) and local NHS England teams [52].

This study will adopt an exploratory research design to investigate the community pharmacy setting as an option for the delivery of Diabetes Prevention Programmes from the views and perceptions of stakeholders and commissioners [53]. Exploratory research is often used to tackle research topics on which little or no previous research has been done [53]. It is usually undertaken in a preliminary stage of an investigation to gain background information, produce insights of the situation being developed and generate ideas [53, 54]. Since there is, to our knowledge, no research investigating community pharmacy as a setting for the delivery of diabetes prevention programmers, an exploratory research design is fitting. This research will involve conducting interviews and focus groups with stakeholders in a stepped process to gain background information about the current role of the community pharmacy and to gain insights that will enable the characterization of its potential role in diabetes prevention.

The topic guide for the interviews and focus groups will be underpinned by the COM-B model proposed by Mitchie *et al* [50]. This model proposes that people need Capability, Opportunity and Motivation to perform a behaviour and was developed to gain the understanding of behaviour in context and develop behaviour targets as a basis of intervention design. Capability explores physical and psychological factors such as taking measurements and knowledge that could enable individuals to enact a behaviour. Opportunity explores physical and social factors such as time, resources and cultural norms that enables a behaviour. Motivation explores mechanisms that may activate or inhibit the want or need to perform a certain behaviour more than any others. The use of the COM-B in this research will therefore assist the identification of behaviour sources that could be fruitful targets for a community

pharmacy diabetes prevention intervention. The COM-B model forms the hub of a Behaviour Change Wheel developed from 19 frameworks of behaviour change identified in systematic literature review (see figure 1) [50].

Fig 1: The Behaviour Change Wheel



3.1 Participant Recruitment

3.1.1 Community pharmacists and support staff

Gatekeeper consent will be sought from area managers of multiple pharmacies (Lloyds, Boots, Well) or pharmacist managers for independent pharmacies. Area managers/pharmacist manager will be sent an e-mail (appendix 1) asking them to circulate an invitation letter (appendix 2) and a participant information sheet (appendix 3) to pharmacists in their area/store. Where gatekeepers are not able to do this, the researcher will seek consent from the gatekeepers to contact community pharmacies via telephone before sending research documents to interested persons.

Individuals who are interested will be asked to complete an online expression of interest form (appendix 4) which will contain options for their availability. After two weeks, the researcher will contact the pharmacies that have not responded via telephone to remind them to complete the expression of interest form if interested to participate in the research.

Inclusion criteria:

1. Community pharmacies in Norfolk and Norwich

2. Registered pharmacists or pre-registration pharmacists involved in the delivery of community pharmacy based public health services (e.g. diabetes screening, NHS Health Checks, smoking cessation)
3. Registered pharmacy technician, dispenser or healthcare assistants involved in the delivery of community pharmacy based public health services

Exclusion criteria

- Non-English speaking

3.1.2 GPs and practice nurses

GP practice participants will be approached through the Norfolk and Suffolk Primary and Community Care Research and Development (R and D) office (appendix 1). Research information, including an invitation letter (appendix 2) and a participant information sheet (appendix 3), will be e-mailed to practice managers by the R and D officers asking them to forward it to GPs and nurses in their practice. Individuals who are interested will be asked to complete an online expression of interest form (appendix 4) which will contain options for their availability. After two weeks those who have not responded will be sent a follow-up e-mail (appendix 5).

Inclusion criteria:

1. GP practices in Norfolk and Norwich
2. Practice nurses and GPs working in a practice involved in screening for prediabetes and referral

Exclusion criteria

- Non-English speaking

3.1.3 Commissioners

Commissioners will be identified through the Norfolk and Suffolk Primary and Community Care Research and Development (R and D) office and/or existing contacts with CCGs and Local Pharmaceutical Committee (LPC). Potential participants will be approached via e-mail (appendix 1) with an attached participant information sheet (appendix 3). Individuals who are interested in participating will be asked to complete an online expression of interest form (appendix 4). After two weeks those who have not responded will be sent a follow-up e-mail (appendix 5).

Inclusion criteria:

- Commissioners in Norfolk and Norwich

- Individuals working for the CCG or LPC who are involved in negotiating for or commissioning local public health services
- Individuals working for local authorities, strategic clinical networks, NHS England and Public Health England who are involved in commissioning local public health services

Exclusion criteria:

- Non-English speaking

3.2 Data collection

Data collection will be undertaken in two phases to aid the exploration of the community pharmacy setting as an option for the delivery of diabetes prevention programmes (see section 3.2.1) and will adopt a mixture of interviews and focus groups. Semi-structured interviews will be adopted rather than open ended interviews to facilitate the gathering of focused subjective textual data [55]. The use of focus groups will allow the generation of data from the interaction of participants' views and perceptions in reflection of the group discussions [55].

In the expression of interest form, participants will be given an option to participate in one, two or both phases of the study. Following the receipt of expression of interest forms from interested individuals, the researcher will organise suitable times and dates of the interview/focus groups with the help of the gatekeepers. Individuals who have expressed interest in taking part will be sent an e-mail reminder (appendix 6) or contacted by telephone (community pharmacy) a week before the agreed date. Interviews will take place at the University of East Anglia or premises convenient to the participants e.g. GP practice. Focus groups will take place in at the University of East Anglia.

3.2.1 Data collection phases

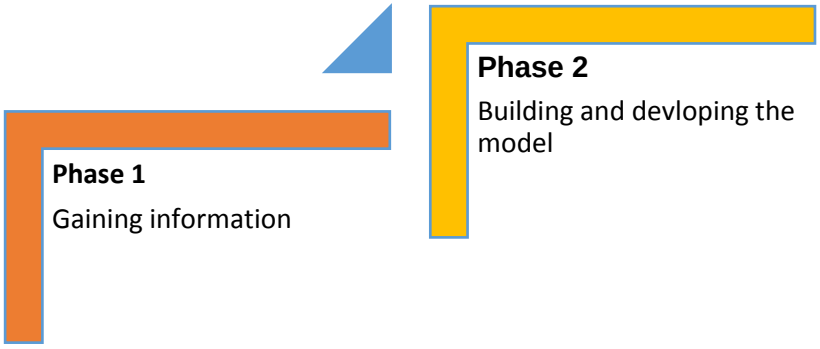
Interviews and focus groups will be conducted over two phases (Fig 2).

Phase 1: This phase will be used to gain information about the current and potential role of the community pharmacy in diabetes prevention. It will also explore the main barriers and facilitators of delivering a community pharmacy-based diabetes prevention programme. The data will be collected primarily using focus groups. However, in order to provide more flexibility and to increase the likelihood of participation, GP practice staff and commissioners will also be given an option of semi-structured interviews. This option will not be available for community pharmacy staff because the dynamic that focus groups provide is crucial for exploring barriers and facilitators in this group of participants who often work as a team to deliver public health services. Two focus groups will be conducted, each

consisting of 6–8 participants. Up to twelve interviews will be conducted, if necessary, for GPs, nurses and commissioners.

Phase 2: The second phase will explore the development of a community pharmacy-based DPP model by building on the findings from the initial phase. One focus group, adopting the Nominal Group Technique (NGT) method will be conducted. The focus group will consist of a mixture of pharmacists, GPs, nurses and commissioners to make up to 6-8 participants. The NGT is a consensus method, often applied in research that is directed at the identification of research priorities [56]. The method aims to achieve a general agreement or convergence of opinion around a particular topic [57]. Therefore, adopting this method at this stage will assist in prioritising research items for the modelling process.

Figure 2: Interview and focus group iterative data collection process



3.2.4 Interview and focus group procedures

3.2.4.1 Semi-structured interviews

Semi-structured interviews will be conducted by the chief investigator (TK) and will take up to a maximum of 60 minutes. According to Blaxter *et al* this is the adequate time to obtain quality and rich interview data [58]. Face to face interviews will be conducted at the University of East Anglia in a private office/meeting room or GP practices or commissioners' offices as per their preference. Interviews will be audio recorded using two recorders and to facilitate the interviews a semi-structured topic guide will be used (appendix 7).

3.2.4.1 Focus groups

Focus groups will be conducted by two members of the research team (TK and MT) and will last approximately 90 minutes. The venue of the focus group will be

arranged by the research team and will take place at the University of East Anglia. Focus groups will be arranged at a time that is convenient for most of the participants. The discussions will be audio recorded using two recorders. Two topic guides (appendix 7 and appendix 10) will be used to facilitate the discussion for the two phases (respectively) with probing questions to ensure that issues relevant to the research topic are covered in depth. Participants in phase 2 will be provided with research findings before the focus group to assist in the ranking process of the NGT Process.

3.2.4.1 General information

Following introductions, the researcher will introduce the research topic explaining the aims and objectives of the research, the purpose of the discussion and what the interview/focus group will cover. Before seeking informed written consent (appendix 8) the researcher will again explain the voluntary nature of the research and arrangements for confidentiality. The researcher will also explain that the interview will be recorded for research analysis purposes. The participants will be informed by the researcher when the recorders are switched on and off. The researcher may also take fields notes during or following every interview/focus group in order to assist analysis and to demonstrate reflexivity.

For focus groups the researcher will also explain that information discussed within the focus group should be regarded as confidential and should not be repeated outside. The researcher will also communicate the ground rules, stressing the importance of not talking over one another to allow the full account of the discussion to be captured by the audio recorders. The role of the researcher will be to encourage an open interactive discussion and to also control the discussion by bringing everyone in, preventing dominant participants and steering the group away from irrelevant topics. Following the interview/focus group the researcher will thank the participant (s) and explain what happens next with the data and reporting. At this time any questions raised by the interviewee will be addressed and contact details for information and support services will also be given.

Nominal Group Technique focus group procedures

Step 1: Individual responses (15 minutes)

Participants will be informed of the purpose of the focus group (i.e. to determine the most important factors that would influence the delivery of community pharmacy-based diabetes prevention services (DPS) and will be given a brief description of the NGT process via e-mail [56]. Participants will also be provided with the topic guide for the discussion (Appendix 10) including a list of factors identified in phase 1 and will be asked to rank in order of importance what factors would enhance the capability, opportunity and motivation of community pharmacy

teams to deliver DPS. The participants will then be asked to e-mail their responses to the facilitator prior to the group discussion. The ranking process will be anonymous.

Step 2: Discussion (Round robin and clarification) (30-40 minutes)
On the day of the focus group, the facilitator will ask one participant at a time to talk about their ranking to the group in a 'round robin' fashion. Participants will then be asked to discuss the rationale behind their ranking with the group as this helps to highlight any ambiguities in the statements that may have affected response and therefore subsequent consensus [56, 57].

Step 3: Re-ranking responses (10-20 minutes)
At this point the participants would have had the opportunity to reconsider their ranking in light of other participants' views. The facilitator will summarise the main discussion points and provide participants with a ranking sheet, where they will be asked to select their top preferences now that they would have had the chance to consider other views. The ranking process will be anonymous.

3.3. Sampling

Convenience sampling will be used to recruit participants from the CCGs and GP practices. However, to gain the perspective of pharmacy staff from all multiples and independents, a purposive sampling method will be used. Focus groups will consist of 6 to 8 participants ensuring a group composition that will aid discussion and ensure an element of diversity to help generate richer discussion [55]. Diversity will also be sought using age, experience and workplace [55]. Participants that have expressed an interest but are not sampled for inclusion will be sent a thank you e-mail (appendix 9) stating that they will not be required to take part.

3.4 Data analysis

3.4.2 Interviews and focus groups

Interviews and focus group recordings will be transcribed verbatim by a member of the research team and inputted into NVivo where it will be analysed using thematic analysis, a method for identifying, analysing and reporting themes within data [59, 60]. This approach has been adopted because it can be used to analyse data from different types of communication media, providing a flexible approach to analyse data from both audio recorded interviews and focus groups [59]. To provide an iterative process of analysis that will be conducted following each phase of the data collection procedure, Braun and Clarkes 6 phases of thematic analysis will be used [60].

Step 1: Familiarisation
Data will be transcribed verbatim by a member of the research team. The transcripts will be checked by another member of the research team. Any disagreements will be resolved by consensus referring back to the original recordings. The researcher will read and re-read each transcript to gain an overview of the content and identify topics and subjects that are of interest and that are linked to the research questions.

Step 2: Inductive coding
Data from the transcripts will be re-read and carefully analysed in order to develop codes according to the research question. The transcribed data will be coded by the main researcher (TK) and checked by another member of the research team. Any disagreement will be agreed by consensus, referring back to the original recordings.

Step 3: Development of themes
Relationships between the codes will be sought in order to develop themes. The development of themes will be aided by the COM-B model and the research questions. Themes will be developed by the main researcher (TK) and for confirmability themes will be checked by research supervisor (MT).

Step 4: Reviewing themes
Transcripts will be re-read by the main researcher (TK) to ensure that correspondence and accuracy between the developed themes and the data. At this point iterative judgements may be made in order to give a more accurate description of the themes e.g. extracts may be moved to other codes and themes. The researcher will also use field notes to assist the accurate description of the themes.

Step 5: Defining themes
Each theme will be given a name which captures the essence of the contents and a detailed analysis of each theme will be written. Transcripts will again be revisited to identify representative extracts to use in the written analysis of each them.

Step 6: Reporting
A clear and concise narrative of the themes will be written using extracts identified in step 5 as illustrative evidence of the themes. This will ensure authenticity of the findings. Codes and themes generated from each phase will contribute to the development of a community pharmacy-based model.

3.4.2.1 Nominal Group Technique ranking

The scores of the ranking will be totalled by the research team in order to identify research topics that will be taken forward to assist the development of community pharmacy-based diabetes prevention services. Following the identification of research items, the research team will use the COM-B model to identify

intervention functions and consequent behaviour change techniques that could be adopted by the community pharmacy teams in order to deliver diabetes prevention programmes.

4.0 Ethics

4.1 Approval

Ethics and governance approval will be obtained from the Faculty of Medicine and Health Sciences Research Ethics committee at the University of East Anglia and the Health Research Authority (HRA) before commencing the research. All data will be dealt as per University of East Anglia data protection policy to ensure confidentiality (anonymity).

4.2 Ethical considerations

Overall risks in this study are relatively low. We will obtain fully informed consent from the participants, giving them two weeks to read the participant information sheet before deciding to participate. Information in the participant information sheet particularly the voluntary nature of the research, confidentiality, anonymity and their right to withdraw from the study will be reiterated before asking them to sign the consent form. Interview participants will be free to withdraw at any point of the study and data collected up to the point of leaving will only be included in the analysis with their consent. Focus group participants will also be free to withdraw at any point of the study but data collected up to the point of leaving will not be withdrawn from the analysis. Where participants reveal illegal information or unacceptable behaviors, the interview of focus group will be drawn to a close and steps to ensure the researchers safety (below) will be carried out. The chief investigator (TK) has undertaken a Good Clinical Practice training in 2015 as part of an MSc in clinical research degree. This will ensure that the researcher is competent to perform the tasks of this research and is also qualified by education, training and experience.

4.2.1 Informed consent

We will obtain fully informed consent from the participants, giving them two weeks to read the participant information sheet before deciding to participate. Before conducting each interview/focus group the researcher will obtain written informed consent from the participants. Obtaining consent will be conducted at the start of the interviews/focus group following an introduction of the research topic by the researcher and an explanation of the voluntary nature of the research and arrangements for confidentiality.

4.2.2 Researcher safety

The research poses a low risk for the researcher's safety since face to face interviews will only be conducted at the University or GP practice or commissioners' offices whilst focus groups will be conducted by two members of the research team. Face-to-face interview appointments will be scheduled during working hours when possible. The researcher will notify a member of the research team (by text) once she has reached the interview venue and when interview is completed. Arrangements will be made to contact the researcher if they have not heard from them following a certain period of time. If an interview appointment is delayed for any reason a member of the research team will be notified and if at any point the researcher becomes uncomfortable actions will be taken to conclude the interview and leave immediately.

The researcher has attended a personal and professional development course at UEA on Researchers Personal Safety. This session offered practical advice about possible hazards that need consideration including minor annoyances that can escalate into verbal and physical confrontations, and techniques to de-escalate or ideally avoid such situations. The session covered safe working strategies that will be implemented by the research team to ensure researchers safety.

4.2.3 Storage of data

Data from the study will be processed as per UEA data management policy [61]. Data obtained will be solely used for the purposes of this study and will not be processed in a manner incompatible with this. Data will be adequate, relevant and not excessive.

All audio files will be downloaded and stored on a password protected computer and filed under participant reference before being removed from the digital recorder. Consent forms will be kept in a secured locked filing cabinet in an office at UEA. All personal data including audio recordings and consent forms will be stored for 3 years or when the PhD thesis is complete. This is to enable the researcher to check the recordings whilst the reports are being written. Transcripts will be anonymized and stored on a secure password protected computer. Research data (transcripts) will be kept for 10 years as per UEA policy.

4.2.4 Confidentiality

All data will be dealt with to ensure confidentiality and anonymity. Recorded data will only be listened to by the researcher and members of the supervisory team. Transcripts will have all personal and identifiable data removed and will only be analyzed by members of the research team. When reporting the results, any quotes used will be anonymous and will be assigned a reference number e.g. I-01 or FG-01.

4.2.5 Duty of care

Where issues emerge during the interview(s) or focus group(s) that are considered potentially harmful or dangerous to others or those in their care the researcher might consider the need to break confidentiality. In this circumstance, the main researcher will discuss the need to disclose the information with the supervisor and if necessary the research team prior to deciding what action to take.

4.2.6 Incentives and reimbursement

Participants will be reimbursed for participation and travel costs. For the focus groups and interviews, all participants will receive a £30 voucher for participating. Where GP practice staff opt to have interviews conducted at the practices, practices will be reimbursed at £80 per hour for GP time and nurses £23.21 per hour for nurses time. Other participants e.g. CCG participants who opt for interviews will also be reimbursed at £30 per hour. Refreshments will be provided for the focus groups.

5.0 Dissemination

The findings in this study will be disseminated to healthcare professionals particularly pharmacists at relevant conferences e.g. Health Services Research and Pharmacy Practice UK and International Social Pharmacy Workshop. The findings will also be communicated locally through the Norfolk and Norwich CCG. Nationally we will communicate the findings to the programme director of the NHS DPP who has expressed interest in our study focus. We also hope to publish the findings of this research in a peer reviewed journal.

6.0 Timescale

This study is being conducted as part of a PhD which commenced in June 2016. The research is planned to be conducted until the end of the three year period which is July 2019 from protocol write-up to dissemination. See Table 1.

Table 1 Study timeline

Second project: qualitative research	**2017**					**2018-19**										
Activity details	**Aug**	**Sept**	**Oct**	**Nov**	**Dec**	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Dec-Jul**
Protocol write-up																
Engagement with gatekeepers																
Ethics submission																
Recruiting																
Phase 1																
Data analysis (Phase 1)																
Phase 2																
Data analysis (Phase 2)																
Report writing																
Dissemination of results																

References

1. World Health Organisation, *Global status report on noncommunicable diseases*. 2014: Geneva, Switzerland.
2. International Diabetes Federation, *Diabetes Atlas*. 2006, Brussels.
3. Public Health England, *Diabetes prevalence model*. 2016, Public Health England: London.
4. Hex N, et al., *Estimating the current and future costs of Type 1 and Type 2 diabetes in the UK, including direct health costs and indirect societal and productivity costs.* Diabet Med, 2012. **29**(7): p. 855-62.
5. National Cardiovascular Intelligence Network (NCVIN), *NHS Diabetes Prevention Programme (NHS DPP) Non-diabetic hyperglycaemia*. 2015, Public Heakth England London
6. NICE, *Type 2 diabetes: prevention in people at high risk. Public health guideline*, N.I.f.H.a.C. Excellence, Editor. 2012.
7. Health and Social Care Information Centre, *Statistics on Obesity, Physical Activity and Diet – England, 2016* 2016, Health and Social Care Information Centre: Leeds.
8. Diabetes UK. *Position Statement. Prevention of type 2 diabetes: whole-society interventions to reduce obesity*. 2015; Available from: https://www.diabetes.org.uk/Documents/Position%20Statement%20-%20Prevention%20of%20Type%202%20diabetes;%20whole-society%20interventions%20to%20reduce%20obesity.pdf.
9. Forouzanfar M and *et. al*, *Global, regional, and national comparative risk assessment of 79 behavioural, environmental and occupational, and metabolic risks or clusters of risks in 188 countries, 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013.* The Lancet, 2015. **386**(10010): p. 2287-2323.
10. Stolk, R.P., *Screening for diabetes.* BMJ, 2007. **335**(7618): p. 457-458.
11. Finnish Diabetes Association, *Programme for the prevention of type 2 diabetes in Finland 2003-2010*. 2003: Finland.
12. Ashra, N.B.S., R.; Carter, P.; Davies, M. J.; Dunkley, A. et.el. , *A systematic review and meta-analysis assessing the effectiveness of pragmatic lifestyle interventions for the prevention of type 2 diabetes mellitus in routine practice.* 2015.
13. Orozco, L.J., et al., *Exercise or exercise and diet for preventing type 2 diabetes mellitus.* Cochrane Database Syst Rev, 2008(3): p. CD003054.
14. Nuzhat B Ashra, R.S., Patrice Carter, Melanie J Davies et al, *A systematic review and meta-analysis assessing the effectiveness of pragmatic lifestyle interventions for the prevention of type 2 diabetes mellitus in routine practice.* 2015.
15. Li, G., et al., *The long-term effect of lifestyle interventions to prevent diabetes in the China Da Qing diabetes prevention study: a 20-year follow-up study.* Lancet, 2008. **371**.
16. Ramachandran, A., et al., *The Indian Diabetes Prevention Programme shows that lifestyle modification and metformin prevent type 2 diabetes in Asian Indian subjects with impaired glucose tolerance (IDPP-1).* Diabetologia, 2006. **49**(2): p. 289-297.

17. Knowler, W.C., et al., *Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin.* N Engl J Med, 2002. **346**.
18. Lindstrom, J., et al., *The Finnish Diabetes Prevention Study (DPS): Lifestyle intervention and 3-year results on diet and physical activity.* Diabetes Care, 2003. **26**.
19. Ali, M.K., J. Echouffo-Tcheugui, and D.F. Williamson, *How effective were lifestyle interventions in real-world settings that were modeled on the diabetes prevention program?* Health affairs, 2012. **31**.
20. Dunkley, A.J., D.H. Bodicoat, and C.J. Greaves, *Diabetes prevention in the real world: effectiveness of pragmatic lifestyle interventions for the prevention of type 2 diabetes and of the impact of adherence to guideline recommendations: a systematic review and meta-analysis.* Diabetes Care, 2014. **37**.
21. Gillies, C.L., K.R. Abrams, and P.C. Lambert, *Pharmacological and lifestyle interventions to prevent or delay Type 2 diabetes in people with impaired glucose tolerance : systematic review and meta –analysis.* Br Med J, 2007. **334**.
22. Taylor, J., et al., *Identifying risk and preventing progression to type 2 diabetes in vulnerable and disadvantaged adults: a pragmatic review.* Diabetic medicine : a journal of the British Diabetic Association, 2013. **30**.
23. Orozco, L.J., et al., *Exercise or exercise and diet for preventing type 2 diabetes mellitus*. 2008.
24. Yamaoka, K. and T. Tango, *Efficacy of lifestyle education to prevent type 2 diabetes: a meta-analysis of randomized controlled trials.* Diabetes care, 2005. **28**.
25. Yates, T., et al., *The role of physical activity in the management of impaired glucose tolerance: a systematic review.* Diabetologia, 2007. **50**(6): p. 1116-26.
26. Barry, E., et al., *Efficacy and effectiveness of screen and treat policies in prevention of type 2 diabetes: systematic review and meta-analysis of screening tests and interventions.* BMJ, 2017. **356**.
27. Gillett, M., et al., *Non-pharmacological interventions to reduce the risk of diabetes in people with impaired glucose regulation: a systematic review and economic evaluation.* Health technology assessment, 2012. **16**.
28. Aziz, Z., et al., *A systematic review of real-world diabetes prevention programs: learnings from the last 15 years.* Implementation Science, 2015. **10**(1): p. 172.
29. Whittemore, R., *A systematic review of the translational research on the Diabetes Prevention Program.* Translational behavioral medicine, 2011. **1**(3): p. 480-491.
30. Public Health England, *Consolidating and developing the evidence base and research for community pharmacy's contribution to publuc health: a progress report from Task Group 3 of the Pharmacy and Public Health Forum*. 2014, Public Health England London.
31. Twigg, M.J., et al., *Community pharmacy type 2 diabetes risk assessment: demographics and risk results.* Int J Pharm Pract, 2015. **23**(1): p. 80-2.

32. Corlett, S.A. and J. Krska, *Evaluation of NHS Health Checks provided by community pharmacies.* J Public Health (Oxf), 2015.
33. local Government Association, *Community pharmacy. Local government's new public health role.* . 2013, Local Government Association: London.
34. NHS England, *Improving health and patient care through community pharmacy - a call to action*. 2013.
35. Laws, R.A., et al., *Factors influencing participation in a vascular disease prevention lifestyle program among participants in a cluster randomized trial.* BMC Health Serv Res, 2013. **13**: p. 201.
36. Kullgren, J.T., et al., *Mixed methods study of engagement in behaviors to prevent type 2 diabetes among employees with pre-diabetes.* BMJ Open Diabetes Research & Care, 2016. **4**(1).
37. Penn, L., S.M. Moffatt, and M. White, *Participants' perspective on maintaining behaviour change: a qualitative study within the European Diabetes Prevention Study.* BMC Public Health, 2008. **8**(1): p. 235.
38. Anderson, C., *Health promotion in community pharmacy: the UK situation.* Patient Educ Couns, 2000. **39**(2-3): p. 285-91.
39. Todd, A., et al., *Access all areas? An area-level analysis of accessibility to general practice and community pharmacy services in England by urbanity and social deprivation.* BMJ Open, 2015. **5**(5).
40. Todd, A., et al., *The positive pharmacy care law: an area-level analysis of the relationship between community pharmacy distribution, urbanity and social deprivation in England.* BMJ Open, 2014. **4**(8).
41. Dasgupta, K., et al., *Strategies to Optimize Participation in Diabetes Prevention Programs following Gestational Diabetes: A Focus Group Study.* Plos One, 2013. **8**(7).
42. Morrison, Z., et al., *Understanding experiences of participating in a weight loss lifestyle intervention trial: a qualitative evaluation of South Asians at high risk of diabetes.* BMJ Open, 2014. **4**(6).
43. Gatineau Mary, H.C., Holman Naomi, Outhwaite Helen, Oldridge Lorraine, Christie Anna and Ells Louisa, *Adult obesity and type 2 diabetes*, P. Health, Editor. 2014, Public Health England London.
44. Sargeant, L.A., et al., *Who attends a UK diabetes screening programme? Findings from the ADDITION-Cambridge study.* Diabet Med, 2010. **27**(9): p. 995-1003.
45. DiMaria, L.A., *Understanding the barriers and facilitators of lifestyle intervention programs for preventing diabetes in high risk hispanic adults*, in *Nursing*. 2015, University of Rhode Island USA.
46. Mayega, R.W., et al., *'Change means sacrificing a good life': perceptions about severity of type 2 diabetes and preventive lifestyles among people afflicted or at high risk of type 2 diabetes in Iganga Uganda.* BMC Public Health, 2014. **14**: p. 864.
47. Grace, C., et al., *Prevention of type 2 diabetes in British Bangladeshis: qualitative study of community, religious, and professional perspectives.* BMJ, 2008. **337**.

48. Pharmacy Services Negotiating Committee. *Pharmacy. The heart of our community*. [cited 2016 19th of October]; Available from: http://psnc.org.uk/psncs-work/about-community-pharmacy/.
49. Medical Research Council *Developing and evaluating complex interventions: new guidance* 2006.
50. Michie S., A.L., West R. , *The Behaviour Change Wheel: A Guide to Designing Interventions* 1st ed. 2014, London: Silverback.
51. Pharmaceutical Services Negotiating Committe. *Public health services. Supporting people to live healthier lives*. [cited 2017 25th August]; Available from: http://psnc.org.uk/services-commissioning/locally-commissioned-services/healthy-living-pharmacies/.
52. Pharmaceutical Services Negotiating Committe. *Locally Commissioned Services*. Available from: http://psnc.org.uk/services-commissioning/locally-commissioned-services/.
53. Dudovskiy J. *Research Methodology. Exploratory Reserach* 2017; Available from: http://research-methodology.net/research-methodology/research-design/exploratory-research/.
54. University, L. *Research Methods in the Social Sciences*. 2017 [cited 2017 25th of August]; Available from: http://lynn-library.libguides.com/c.php?g=549455&p=3771805.
55. Jane Ritchie and Jane Lewis, *Qualitative research practice : a guide for social science students and researchers*, ed. J.R.a.J. Lewis. 2003, London: SAGE Publications LTD.
56. McMillan, S.S., M. King, and M.P. Tully, *How to use the nominal group and Delphi techniques.* International Journal of Clinical Pharmacy, 2016. **38**: p. 655-662.
57. Delbecq AL, van de Ven AH, and Gustafson DH, *Group techniques for program planning, a guide to nominal group and Delphi processes*. 1975, Glenview, IL: Foreman and Company
58. Blaxter, L.H., C & Tight, M. , *How to Research: Data Collection (Chapt 6)*. 1996, Great Britain: Open University Press.
59. Nicola Brace, *Investigating Methods: Collecting, Interpreting and Reporting Evidence in Psychology*, ed. J.M.a.N. Brace. 2014: Open University.
60. Virginia Braun and Victoria Clarke, *Using thematic analysis in psychology.* Qualitative Research in Psychology, 2006. **3**: p. 77-101.
61. University of East Anglia, *UEA Research Data Management Policy.*

Appendix 4.2

Initial ethics approvals for the qualitaive study (Chapter 4) and Nominal group technique study (Chapter 6)

Appendix 4.2: Initial HRA Approval

NHS
Health Research Authority

01 November 2017

Dear Miss Katangwe

Letter of HRA Approval

Study title:	**The community pharmacy setting for the delivery of diabetes prevention programmes: views and perceptions of stakeholders**
IRAS project ID:	**233631**
Protocol number:	**TK-MT-Rev1**
Sponsor	**University of East Anglia**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The attached document *"After HRA Approval – guidance for sponsors and investigators"* gives detailed guidance on reporting expectations for studies with HRA Approval, including:

- Working with organisations hosting the research
- Registration of Research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics and is updated in the light of changes in reporting expectations or procedures.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.
If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

Your IRAS project ID is **233631**. Please quote this on all correspondence.
Yours sincerely

Miss Lauren Allen Assessor

E-mail: hra.approval@nhs.net

Copy to: *Mr Samuel Hills (Sponsor contact)*

Claire Symms, Norfolk & Suffolk Primary & Community Care Research Office (Lead NHS R&D contact)

Appendix 4.2: Initial FMH approval

University of East Anglia

Research & Innovation Services
Floor 1, The Registry
University of East Anglia
Norwich Research Park
Norwich, NR4 7TJ

Email: fmh.ethics@uea.ac.uk

Web: www.uea.ac.uk/researchandenterprise

Faculty of Medicine and Health Sciences Research Ethics Committee

Thando Katangwe

PH

16.10.17

Dear Thando,

Title: The community pharmacy setting for the delivery of diabetes prevention programmes: views and perceptions of stakeholders Reference: 2017/18 - 13

Thank you for your e-mail notifying us of the amendments you would like to make to your above proposal. These have been considered and we can now confirm that your amendments have been approved.

Please can you ensure that any further amendments to either the protocol or documents submitted are notified to us in advance, and also that any adverse events which occur during your project are reported to the Committee.

Please can you also arrange to send us a report once your project is completed.

Yours sincerely,

Professor M J Wilkinson

Chair

FMH Research Ethics Committee

Amendment ethical approvals

Appendix 4.3

Ethics amendment approvals for the qualitaive study (Chapter 4) and nominal group technique study (Chapter 6)

Appendix 4.3: HRA approval for amendment number one

Amendment Categorisation and Implementation Information

Dear Dr Katangwe,

Thank you for submitting an amendment to your project.

If you have participating NHS/HSC organisations in any other UK nations we will forward the information to the relevant national coordinating function(s). Please note that you may only implement changes described in the amendment notice.

What Happens Next?

Information Specific to Participating NHS Organisations in England

1. You should now share details of the amendment and, if applicable, amended documents, together with this e-mail, with all participating NHS organisations in England. In doing so, you should include the NHS R&D Office, LCRN (where applicable) as well as the local research team. A template e-mail to notify participating NHS organisations in England is provided on the HRA website.
2. The participating NHS organisations in England should prepare to implement this amendment.
3. Your amendment has been assessed against HRA standards. **This e-mail also constitutes HRA Approval for the amendment, and you should not expect anything further from the HRA.**
4. You may implement your amendment at all participating NHS organisations in England 35 calendar days from the day on which you provide the organisations with this e-mail and your amended documents (or as soon as the participating NHS organisation confirm that you may implement, if sooner). **NHS organisations do not have to confirm they are happy with the amendment.**
5. You may not implement the amendment at any participating NHS organisations in England that requests additional time to assess, until it confirms that it has concluded its assessment.
6. You may not implement at any participating NHS organisation in England that declines to implement the amendment.

IRAS Project ID:	233631
Short Study Title:	The role of community pharmacy in diabetes prevention - parallel study
Date complete amendment submission received:	21/02/2018
Amendment No./ Sponsor Ref:	Amendment no. 1
Amendment Date:	14 February 2018
Amendment Type:	Non-substantial

Outcome of HRA Assessment	**This e-mail also constitutes HRA Approval for the amendment,** and you should not expect anything further from the HRA.
Implementation date in NHS organisations in England	35 days from date amendment information together with this e-mail, is supplied to participating organisations
For NHS/HSC R&D Office information	
Amendment Category	**A**

If you have any questions relating to the wider HRA approval process, please direct these to hra.approval@nhs.net.

If you have any questions relating to this amendment in one of the devolved administrations, please direct these to the relevant national coordinating function.

Additional information on the management of amendments can be found in the IRAS guidance.

Please do not hesitate to contact me if you require further information.

Kind regards

Mr Ali Hussain
Amendments Co-ordinator
Health Research Authority
Ground Floor | Skipton House | 80 London Road | London | SE1 6LH
E.hra.amendments@nhs.net
W. www.hra.nhs.uk

Appendix 4.3: HRA approval for amendment number two

Dear Samuel,

IRAS Project ID:	233631
Short Study Title:	The role of community pharmacy in diabetes prevention - parallel study
Amendment No./Sponsor Ref:	AM02
Amendment Date:	18 December 2018
Amendment Type:	Non Substantial Non-CTIMP

I am pleased to confirm **HRA and HCRW Approval** for the above referenced amendment. You should implement this amendment at NHS organisations in England and Wales, in line with the conditions outlined in your categorisation e-mail.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/.

Please contact hra.amendments@nhs.net for any queries relating to the assessment of this amendment.

Kind regards,

Natalie

Natalie Wilson

Assessor

Health Research Authority

HRA | NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle-upon-Tyne | NE2 4NQ

Appendix 4.3: FMH approval for amendment number one

Faculty of Medicine and Health Sciences Research Ethics Committee

University of East Anglia

Research & Innovation Services
Floor 1, The Registry
University of East Anglia
Norwich Research Park
Norwich, NR4 7TJ

Email: fmh.ethics@uea.ac.uk

Web: www.uea.ac.uk/researchandenterprise

Thando Katangwe
PHA

5.3.18

Dear Thando,

Title: The community pharmacy setting for the delivery of diabetes prevention programmes: views and perceptions of stakeholders Reference: 2017/18 - 13

Thank you for your e-mail notifying us of the amendments you would like to make to your above proposal. These have been considered and we can now confirm that your amendments have been approved.

Please can you ensure that any further amendments to either the protocol or documents submitted are notified to us in advance, and also that any adverse events which occur during your project are reported to the Committee.

Please can you also arrange to send us a report once your project is completed.

Yours sincerely,

Professor M J Wilkinson
Chair

Appendix 4.3: FMH approval for amendment number two

FMH Research Ethics Committee

Thando Katangwe
PHA

University of East Anglia

Research & Innovation Services
Floor 1, The Registry
University of East Anglia
Norwich Research Park
Norwich, NR4 7TJ

Email: fmh.ethics@uea.ac.uk

Web: www.uea.ac.uk/researchandenterprise

19 December 2018

Dear Thando

Title: The community pharmacy setting for the delivery of diabetes prevention programmes: views and perceptions of stakeholders
Reference: 2017/18 - 13

Thank you for your e-mail of 18 December notifying us of the amendments you would like to make to your above proposal. These have been considered and we can now confirm that your amendments have been approved.

Please can you ensure that any further amendments to either the protocol or documents submitted are notified to us in advance, and also that any adverse events which occur during your project are reported to the Committee.

Approval by the FMH Research Committee should not be taken as evidence that your study is compliant with GDPR and the Data Protection Act 2018. If you need guidance on how to make your study GDPR compliant, please contact your institution's Data Protection Officer.

Please can you also arrange to send us a report once your project is completed.

Yours sincerely,

Professor M J Wilkinson
Chair
FMH Research Ethics Committee

Appendix 4.4

Research and Development (R&D) office approvals for the qualittaive study (Chapter 4) and nominal group technique study (Chapter 6

Appendix 4.4: R &D Initial study approval

Dear Thando

Full Study Title: 2017GP40 (233631). The role of community pharmacy in diabetes prevention - parallel study

This e-mail confirms the research office has registered the above referenced study for information and we are happy for you to approach GP practices and pharmacies in Norfolk; North Norfolk CCG; Norwich CCG and South Norfolk CCG if needed.

Once your study has completed, we would be grateful if you could forward a copy of the final report, a one page lay summary and any publications associated with the study to snccg.randdoffice@nhs.net or CAPCCG.RandDoffice@nhs.net for dissemination. May we take this opportunity to wish you well with your research and we look forward to hearing the outcomes for the study. Please note the reference number for this study is **Ref: 233631** and this should be quoted on all correspondence.

Kind regards

Clare Symms
Norfolk and Suffolk Office
Research Management and Finance Lead

Appendix 4.4: R & D Approval for amendment number one

Dear Thando

Re: Arrangements to support the below amendment in Norfolk Pharmacies, Norfolk GP Practices and Norfolk CCGs (North Norfolk, Norwich and South Norfolk)

Full Study Title: 2017GP40 (IRAS 233631) The community pharmacy setting for the delivery of diabetes prevention programmes: views and perceptions of stakeholders

Type	Title	Date of Amendment	Date of HRA Approval	Summary of Amendment
Non substantial	Amendment 1	14/02/18	25/02/18	Increase in number of participants for each project phase; inclusion of local authority, clinical networks, NHS England and Public Health England; revision of timeline of study to 18 months.

We acknowledge receipt of this amendment for which **regulatory and HRA approvals are in place** and are happy for it to be implemented in **Norfolk pharmacies, GP practices and CCGs.**

It is a sponsor responsibility to communicate the changes to sites as per the HRA e-mail dated 25/02/18.

Kind regards

Clare Symms
Norfolk and Suffolk Office
Research Management and Finance Lead

Appendix 4.4: R & D Approval for amendment number two

Dear Thando

Arrangements to support the below amendments in Norfolk GP Practices

Full Study Titles: 2017GP29 (227930) Community pharmacy in diabetes prevention

Study	Type	Title	Date of Amendment	Date of HRA Approval	Summary of Amendment
2017GP40 (IRAS 233631) The role of community pharmacy in diabetes prevention - parallel study	Non substantial	Am02	18/12/18	19/12/18	As above

We acknowledge receipt of these amendments for which **regulatory and HRA approvals are in place** and are happy for these to be implemented in **Practices.** It is a sponsor responsibility to communicate the changes to sites as per the HRA e-mails dated 19/12/18 and 03/01/19.

Kind regards

Clare Symms

Norfolk and Suffolk Office

Research Management and Finance Lead

Appendix 4.5

Gatekeeper consent letters

Appendix 4.5: Gatekeeper consent letter (community pharmacy support staff)

University of East Anglia

Subject Heading: The community pharmacy setting for the delivery of diabetes prevention programmes: views and perceptions of stakeholders

Dear Sir/Madam,

My name is Thando Katangwe and I am a research pharmacist undertaking a PhD at the University of East Anglia. My research is looking at the role of the community pharmacy in the prevention of type 2 diabetes and is specifically exploring this setting as an option for the delivery of diabetes prevention programmes.

As part of this research, I would really value views and input from community pharmacy teams in Norfolk and Norwich, including pharmacists and support staff (e.g. dispensers, healthcare assistants) who are currently involved in delivering public health or local services. To this end, I am seeking your consent to approach community pharmacies in your area to recruit for my study which involves focus group discussions.

I would appreciate it if you could circulate the invitation letter and participant information sheet attached to this e-mail to pharmacists and support staff in your area. This documentation explains a bit more about what the research involves and how they can participate. If it is not possible to circulate this information, with your consent, I would be happy to approach the pharmacies by contacting them via telephone to explain the research before posting them this documentation.

The research will be undertaken at the UEA and will take place outside working hours. Each participant will be given a £30 voucher as a thank you for their time. If you have any questions, please don't hesitate to contact me via e-mail (T.Katangwe@uea.ac.uk) or telephone (01603591973).

I look forward to hearing from you,

Kind regards,

Miss Thando Katangwe
Research Pharmacist, School of Pharmacy
University of East Anglia, Norwich, NR4 7TJ
Tel: 01603591173

Appendix 4.5: Gatekeeper consent letter (General practice)

University of East Anglia

Subject Heading: The community pharmacy setting for the delivery of diabetes prevention programmes: views and perceptions of stakeholders

Dear Sir/Madam,

My name is Thando Katangwe and I am a research pharmacist undertaking a PhD at the University of East Anglia. My research is looking at the role of the community pharmacy in the prevention of type 2 diabetes and is specifically exploring this setting as an option for the delivery of diabetes prevention programmes.

As part of this research, I am conducting interviews or focus groups with potential stakeholders, including GPs and nurses. I would really value their views and input on the current and the potential role of the community pharmacy in diabetes prevention. To this end, I would appreciate it if you could circulate the attached invitation letter and participant information sheet to GPs and nurses in your practice.

This research will involves interviews (30-60 minutes) or focus groups (60-90 minutes) which will take place in workplaces or at the UEA respectively. Practices will be reimbursed for GPs and nurses time if the interviews are conducted during work time. If they chose to participate in focus groups, each participant will be given a £30 voucher as a thank you for their time. If you have any questions please don't hesitate to contact me via e-mail (T.Katangwe@uea.ac.uk) or telephone (01603591973).

I look forward to hearing from you,

Kind regards,

Miss Thando Katangwe
Research Pharmacist, School of Pharmacy
University of East Anglia, Norwich, NR4 7TJ
Tel: 01603591173

Appendix 4.5: Gatekeeper consent letter (commissioners)

Subject Heading: The community pharmacy setting for the delivery of diabetes prevention programmes: views and perceptions of stakeholders

Dear Sir/Madam,

My name is Thando Katangwe and I am a research pharmacist undertaking a PhD at the University of East Anglia. My research is looking at the role of the community pharmacy in the prevention of type 2 diabetes and is specifically exploring this setting as an option for the delivery of diabetes prevention programmes.

As part of this research, I would really value your views as commissioners on the current and potential role of community pharmacy in the prevention of type 2 diabetes. This research will involve interviews or focus groups which could take place at your workplace or at the UEA respectively.

Further information about the research and what it involves is provided in the attached patient information sheet. If you are interested in taking part please complete an online expression of interest form [Link to MS Forms]. If you have any questions please don't hesitate to contact me via e-mail (T.Katangwe@uea.ac.uk) or telephone (01603591973).

I look forward to hearing from you,

Kind regards,

Miss Thando Katangwe
Research Pharmacist, School of Pharmacy
University of East Anglia, Norwich, NR4 7TJ
Tel: 01603591173

Appendix 4.6

Invitation letter

Appendix 4.6: Invitation letter

University of East Anglia

Invite to participate in research - The community pharmacy setting for the delivery of diabetes prevention programmes: views and perceptions of stakeholders

Dear Sir/Madam

My name is Thando Katangwe. I am a research pharmacist undertaking a PhD at the University of East Anglia (UEA). I am currently working on a project to explore the community pharmacy as an option for the delivery of Diabetes Prevention Programmes. As part of the project we would like to gather general views about the current and potential role of the community pharmacy in the prevention of diabetes.

We would like to invite you to participate in an interview that will take approximately 30-60 minutes (or a group discussion that will take approximately 60-90 minutes). If you participate in the interview (or group discussion), reasonable travel costs will be reimbursed together with £30 voucher as a thank you for participating. Dinner and refreshments will also be provided prior the group discussions.

Please read the participant information sheet and if you are interested in participating, please complete the online 'Expression of Interest Form' [insert link to MS forms]. Please complete the form by [insert date two weeks from e-mail date]. If you have any questions, please feel free to contact Thando Katangwe either by e-mail (T.Katangwe@uea.ac.uk) or by telephone (01603 591973).

Thank you in anticipation for your help.

Yours Sincerely,

Miss Thando Katangwe
Research Pharmacist, School of Pharmacy
University of East Anglia, Norwich, NR4 7TJ
Tel: 01603591173

Appendix 4.7

Participant Information Sheet

Appendix 4.7: Participant information sheet

The community pharmacy setting for the delivery of diabetes prevention programmes: views and perceptions of stakeholders

Participant Information Sheet

We would like to invite you to take part in our research study. This information sheet is designed to help you understand this project and what it will involve. It is set out as a series of questions and answers. Please take time to read the following information carefully and if you wish to discuss it with us, please do not hesitate to contact us (T.Katangwe@uea.ac.uk). We suggest this should take no more than 15 minutes. This research is being conducted as part of a PhD by the Principal Investigator, Thando Katangwe.

What is the purpose of the study?

The purpose of this study is to understand the current and potential role of the community pharmacy in the prevention of type 2 diabetes. We would also like to obtain views and perspectives that may help to explore the community pharmacy as a potential setting for the delivery of diabetes prevention programmes.

Do I have to take part?

Taking part is entirely voluntary. The researchers will allow a minimum of two weeks after sending you this information sheet before contacting you to ask if you are still interested. If we do not hear from you after two weeks, we will send you another e-mail or contact you via telephone as a reminder, inviting you to participate. If you do not wish to participate please inform us via the expression of interest form and you will receive no further correspondence from us.

What are the possible benefits of taking part?

The results of this project could be used to improve services that are provided for people at high risk of developing type 2 diabetes. The findings may also help the development of diabetes prevention services provided in the community pharmacy.

What will I have to do?

If you decide to participate in this study you will be invited to participate in an interview or group discussion conducted by the principal investigator (TK). Interviews will last approximately 30–60 minutes and group discussions will last approximately 60–90 minutes and will be managed by the principal investigator and another member of the research team (MT). The interview/group discussion will be audio recorded and will involve three main topics:

- The current role of community pharmacy in the prevention of type 2 diabetes.
- The potential role of community pharmacy in the prevention of type 2 diabetes.
- The barriers and facilitators of delivering a diabetes prevention programme in the community pharmacy setting.

This research consists of 3 phases, you can choose to participate in one, two or all three phases of the study. Phase one will look to gain insight on the current role and also on the potential role of community pharmacy in the prevention of type 2 diabetes. Phase two will build on this information to explore what a community pharmacy DPP could look like and the third phase will seek to refine a model for a community pharmacy diabetes prevention programme that would have been developed from phase one and phase two.

What happens next?

If you decide to take part please fill in the online expression of interest form [insert MS link] which includes choices of times and locations that are most convenient for you. Following the receipt of the expression of interest form, the researcher will contact you with a time and location of the interview/focus group. The researchers will also contact you a week before the scheduled time to as a reminder. If however, the researchers are unable to offer you the phase(s) of your choice, you will receive a letter notifying you that you have not been selected to participate.

Will my taking part in the study be kept confidential?

Yes. All your personal information will be kept strictly confidential in accordance with the Data Protection Act 1998. All recorded information provided by you will be kept anonymous and will be reported in such a way that you cannot be identified. All data will be stored in a locked cabinet at the UEA or on a password protected UEA computer. Your personal data will be destroyed after 3 years or at the end of the PhD and all the research data will be kept for 10 years in line with the UEA Data Protection policy.

However, where issues emerge during the interview(s) or focus group(s) that are potentially harmful or dangerous to others or those under your care, the researcher might consider the need to break confidentiality. In this circumstance, the main researcher will discuss the need to disclose the information with the supervisor and if necessary the research team prior to deciding what action to take.

Will I be able to withdrawal from the study?

You will be free to withdraw from the research at any point. If you decide to leave in the middle of the interview due to time constraints or any other reason you will also be free to remove your data from analysis – we will ask you if you want us to do this. However, if you feel you need to leave in the middle of the group discussion, we will not be able to remove your data and it will be included in the final analysis.

What will happen to the results of the research study?

The findings of the study will be shared with you. This work is being conducted as part of a PhD research project and therefore we intend to report the findings in a thesis and publish the findings in a peer reviewed journal. Any published information will be reported anonymously.

Will I be compensated or reimbursed for taking part?

The research team will give you a £30 voucher as a thank you for participating in the study. If you have to travel especially for the focus group, you will be reimbursed for any travelling costs. It you decide to participate in all three phases of the interview, you will be reimbursed separately for each phase. (GP practice staff – if you decide to participate in interviews during working hours, your practice will be reimbursed at £80 per hour (GPs) or £24 per hour (nurses)).

Are there any disadvantages to take part in the study?

We do not foresee any disadvantages to taking part in the research. However, in the unlikely event that distress is caused by the research process, you will be signposted to an experienced member of the research team.

Who has reviewed the study?

This research has been reviewed and approved by the Health Research Authority and the Faculty of Medicine and Health Sciences Research Ethics committee at the University of East Anglia, to protect your safety, rights, wellbeing and dignity.

Who is funding this research?

This research is being funded by the University of East Anglia and Boots UK.

What if I have a complaint?

If you have any questions about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [01603 591973]. If you remain unhappy and wish to complain formally, you can do this by contacting the Head of School of Pharmacy and Chemistry, Professor Mark Searcey via e-mail: m.searcey@uea.ac.uk or telephone 01603 592026.

For further information please contact:

Principal Investigator
Miss Thando Katangwe
School of Pharmacy
University of East Anglia,
Norwich Research Park,
Norwich, NR4 7TJ, Tel: 01603 591973

Research supervisor
Dr Michael Twigg
School of Pharmacy,
University of East Anglia,
Norwich Research Park
Norwich, NR4 7TJ, Tel: 01603 592015

Appendix 4.8

Expression of interest form

Appendix 4.8: Expression of interest form

(Community pharmacists and support staff)

University of East Anglia

The community pharmacy setting for the delivery of diabetes prevention programmes: views and perceptions of stakeholders

Thank you for expressing an interest in taking part in a focus group for the above research project. Please complete the table below with the requested information. Please note that this information will be kept confidential and will only be used by the researcher to facilitate recruitment to the focus groups.

Personal details (please write)	
Full name	
Gender	
Employer	
Job title	
Number of years working in current role	
Current services providing e.g. health checks	
Research phases of interest (please tick ✓)	
Phase 1: The current and potential role of community pharmacy in diabetes prevention	
Phase 2: Exploring the community pharmacy as a potential setting for the delivery of diabetes prevention programmes	
Phase 3: Refining a model of a community pharmacy-based diabetes prevention programme	
Availability (please tick ✓)	
Wed evenings	
Thurs evenings	
Friday evenings	
Contact details (please write)	
Telephone/mobile number	
E-mail address	

Appendix 4.8: Expression of interest form

(Commissioners and general practice staff)

University of East Anglia

The community pharmacy setting for the delivery of diabetes prevention programmes: views and perceptions of stakeholders

Thank you for expressing an interest in taking part in a focus groups/interviews for the above research project. Please complete the table below with the requested information. Please note that this information will be kept confidential and will only be used by the researcher to facilitate recruitment to the focus groups.

Personal details (please write)	
Full name	
Gender	
Workplace e.g. general practice or CCG	
Job title	
Number of years working in current role	
Research phases of interest (please tick ✓)	
Phase 1: The current and potential role of community pharmacy in diabetes prevention	
Phase 2: Exploring the community pharmacy as a potential setting for the delivery of diabetes prevention programmes	
Phase 3: Refining a model of a community pharmacy-based diabetes prevention programme	
Availability (please tick ✓)	
Wed evenings (focus group)	
Thurs evenings (focus group)	
Friday evenings (focus group)	
Other (interviews during working hours)	
Contact details (please write)	
Telephone/mobile number	
E-mail address	

Appendix 4.9

Follow-up letter

Appendix 4.9: Follow-up letter

University of East Anglia

Invite to participate in research - The community pharmacy setting for the delivery of diabetes prevention programmes: views and perceptions of stakeholders

Dear Sir/Madam

I would like to thank all those who have already responded to this e-mail/letter and expressed an interest to participate in the above-named research. For those who have not yet responded, a copy of the previous e-mail is included below for your reference.

My name is Thando Katangwe. I am a research pharmacist undertaking a PhD at the University of East Anglia (UEA). I am currently working on a project to explore the community pharmacy as an option for the delivery of Diabetes Prevention Programmes. As part of the project we would like to gather general views about the current and potential role of the community pharmacy in the prevention of diabetes.

We would like to invite you to participate in an interview that will take approximately 30-60 minutes (or a group discussion that will take approximately 60-90 minutes). If you participate in the interview (or group discussion), reasonable travel costs will be reimbursed together with £30 voucher as a thank you for participating. Dinner and refreshments will also be provided prior the group discussions.

Please read the participant information sheet and if you are interested in participating, please complete the online 'Expression of Interest Form' https://goo.gl/u8PjRd. If you have any questions, please feel free to contact Thando Katangwe either by e-mail (T.Katangwe@uea.ac.uk) or by telephone (01603 591973).

Thank you in anticipation for your help.

Yours sincerely,

Miss Thando Katangwe
Research Pharmacist, School of Pharmacy
University of East Anglia, Norwich, NR4 7TJ
Tel: 01603591173

Appendix 4.10

Reminder e-mail/letter

Appendix 4.10: Reminder e-mail/letter

University of East Anglia

The community pharmacy setting for the delivery of diabetes prevention programmes: views and perceptions of stakeholders

Dear [insert name]

Thank you for volunteering to participate in the research exploring the community pharmacy setting for the delivery of diabetes prevention programmes.

Please note that the interview/focus group will take place [insert date, time and venue].

The interview/discussion is expected to last approximately 60 minutes/90 minutes.

Refreshments will be provided prior to the focus group.

If you have any questions please do not hesitate to contact me, either by e-mail (T.Katangwe@uea.ac.uk) or by telephone (01603 591973).

Yours sincerely,

Miss Thando Katangwe
Research Pharmacist, School of Pharmacy
University of East Anglia, Norwich, NR4 7TJ
Tel: 01603591173

Appendix 4.11

Consent form

Appendix 4.11: Consent form

University of East Anglia

The community pharmacy setting for the delivery of diabetes prevention programmes: views and perceptions of stakeholders

Interview/focus group consent form

	Please initial box
I confirm that I have read and understand the information sheet dated September 2017 version 1 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
I agree to take part in the above study to explore the community pharmacy setting for the delivery of diabetes prevention programmes.	
I am willing to allow the interview or group discussion to be recorded for the purposes of research analysis and possible publication of findings.	
I understand that data collected during the study will be anonymised and will be stored securely at the University of East Anglia.	
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
I agree to take part in the above study.	

_____ _____

_____

Name of participant Date Signature

_____ _____

_____

Name of person taking consent Date Signature

Appendix 4.12

Interview/focus group topic guide

Appendix 4.12: Interview/focus group topic guide

University of East Anglia

The community pharmacy setting for the delivery of diabetes prevention programmes: views and perceptions of stakeholders

Topic	Stem questions	Prompts
Contextual background	Just to start, can you each tell me a bit about yourself (name and current job role)	
Current role of community pharmacy in diabetes prevention	In your experience what role does the community pharmacy currently play in diabetes prevention?	Services provided – Health Checks and HLP Views and opinions about this role What are the challenges with this role
Capabilities	Do you think the community pharmacy could do more in the prevention of type 2 diabetes?	Physical capabilities e.g. HbA1C, BP, weight measurements Psychological capabilities e.g. training, knowledge
	What are your views on the community pharmacy team being involved in delivering a part or all of the diabetes prevention programme?	Do you think they have the capability to provide this kind of service? Do you think the community pharmacy team the right people to deliver this service? Why?

Opportunities	In your view does the community pharmacy have the opportunity to provide a diabetes prevention programme?	Physical – time, resources, space, cues Social – cultural norms, concepts that influence the way we work. Where do you or society/other HCP think it is normal to provide this type of programme?
Motivation	What are the barriers and facilitators of delivering a diabetes prevention programme in the community pharmacy setting	Other competing interests. Apprehension about delivering the programme
Any other comments	Have you got any other comments or feedback about the community pharmacy?	

Appendix 5.1

Protocol for questionnaire study (Chapter 5)

The potential involvement of community pharmacies in diabetes prevention

Questionnaire Study

Researchers:

Achilleas Riniotis (MPharm student, University of East Anglia)
Olipa Zulu (MPharm student, University of East Anglia)
Sekander Amini (MPharm student, University of East Anglia)
Ceyhan Enver-Osman (MPharm student, University of East Anglia)
Zhyar Said (MPharm student, University of East Anglia)

Supervisors:

Thando Katangwe (PhD student, University of East Anglia)
Dr Michael Twigg (Primary Care Pharmacy Lecturer, University of East Anglia)
Dr Debi Bhattacharya (Senior Lecturer, University of East Anglia)

Version 1; 18/07/18; IRAS ID: 252420

Protocol No.	Revision	Date	Investigator Sig.	Sponsor Sig.	IRAS ID
1		18/07/18	MT	JR	

Introduction

In England, an estimated 2.7 million people are living with type 2 diabetes (1) for which the NHS incurs an annual spend of approximately £8.8 billion (10% of the total NHS budget) (2). Additionally, five million people in England are estimated to have 'pre-diabetes', a term used to denote blood glucose levels above normal range but not high enough for diagnosis of type 2 diabetes (3, 4). Pre-diabetes is not a clinical entity in itself, but rather denotes an increased risk of developing type 2 diabetes. If individuals with pre-diabetes are identified and intensive lifestyle interventions are implemented, the onset of type 2 diabetes may be delayed or even prevented (5-11). In England, the NHS Diabetes Prevention Programme (DPP) was implemented in view of this evidence (12). The programme which is being funded by NHS England was first implemented in 2016 over 27 areas, with an expectation to roll out to the whole country by 2020. The programme identifies people with pre-diabetes through routine GP appointments or retrospective screening of general practice databases and refers them onto a behavioural change intervention offering tailored, personalised help to reduce risk via education, weight loss and exercise. The intervention offers at least 13 education and exercise group sessions of one to two hours over a minimum of 9 months. As primary care based interventions are associated with the lowest attrition and highest reach to the targeted populations (13, 14), this approach is predicted to be an appropriate method of addressing the scale of diabetes risk within the community.

NICE recommends the delivery of DPPs by primary health care teams which include community pharmacy (4). Public health England (PHE) has recognised the potential significant and sustainable impact that community pharmacy could make in reducing the risk of disease, including diabetes, due to high accessibility (11). The NHS Five Year Forward View has also recognised the key role of pharmacy, highlighting that there should be far greater use of pharmacists in prevention of ill health and support for healthy living (15). Delivering a community pharmacy based DPP is therefore in line with the public health agenda for pharmacy. However, to date community pharmacy has only been involved in the delivery of opportunistic diabetes screening (16-18) outside of the national prevention programme.

We have recently conducted qualitative research exploring engagement with the NHS DPP in Norfolk in order to determine whether there is a role for community pharmacy in diabetes prevention. This research has identified accessibility barriers to engagement in the current programme such as location, programme times, transportation, work and social commitments as well as the nature of group-based interventions. This is supported by previous findings exploring engagement in disease prevention programs (19-23). Our research has indicated that community pharmacy could serve as an acceptable option for the delivery of DPPs in people who fail to engage with the NHS DPP due to accessibility barriers. The research also showed the need for community pharmacy-based service to be linked with GP practices and highlighted that GP endorsement may have a significant influence on patient engagement. This finding is supported by a growing recognition that public health interventions delivered in community pharmacy should be integrated in a local primary care and public health network (24, 25). However, our qualitative research, conducted with a small number of practitioners involved in the diagnosis of prediabetes and referral to prevention services, revealed a diverse awareness of community pharmacy

services as well as a range of perceptions about the capacity for community pharmacy to deliver public health interventions such as a diabetes prevention programme.

As a result of our previous qualitative work with patients and professionals, we are in the process of developing a model for diabetes prevention in the community pharmacy. This model will use the Behaviour Change Wheel (26, 27) to underpin the development of strategies to assist patients with changing their behaviour (in this case engaging in a diabetes prevention programme). As this previous work has taken place in a small number of practitioners there is also a need to triangulate these findings in a larger number of professionals before proceeding with further development. At the same time, practitioner views on the current NHS DPP will be described using the APEASE criteria (26). The APEASE criteria can be used to make context-based decisions when designing or evaluating interventions. The criteria recognise that an intervention design is more than effectiveness as all behaviour change operates within a diverse range of social contexts, affordability, practicability, effectiveness, acceptability, sustainability and equity. The APEASE criteria will be useful for establishing a contextual understanding of views on the NHS DPP in order that our interpretation of views on the community pharmacy role in diabetes prevention may be described within this wider context.

Aims and Objectives

Aim

To assess the acceptability and practicality, from a primary care practitioner's perspective, of the NHS DPP and potential role of the community pharmacy in diabetes prevention.

Objectives

1. To conduct a context-based evaluation of the existing diabetes prevention service.
2. To examine the perceived role of community pharmacy in diabetes prevention.
3. To triangulate findings from previous qualitative work in a larger group of practitioners.

Method

This research will involve distributing a short questionnaire to GPs and nurses involved in the management of people with prediabetes together with community pharmacists. The project will be undertaken by five fourth year pharmacy students from the University of East Anglia (UEA) under the guidance of a project supervisor and a PhD student. Ethics and governance approval will be obtained from the Health Research Authority and UEA Faculty of Medicine and Health Sciences Ethics committee prior commencing the research.

Questionnaire rationale

The use of questionnaires has been adopted in this study as the most efficient way, in terms of time and cost, to obtain data from a large sample from a wide geographical distribution (28). It also provides anonymity and thus may encourage honest answers. Having previously conducted qualitative work in this group of practitioners and with a set of defined criteria forming part of the evaluation, a questionnaire approach is deemed appropriate to further progress this study.

Participant recruitment – GPs and nurses

Details of the initial 27 sites across England that have implemented the NHS DPP will be obtained from the NHS DPP website. CCG Research and Development departments in these areas will be contacted via e-mail once the study is approved by UEA and HRA. Each CCG will have a nominated lead for the NHS DPP and as such the R&D department will be asked to forward an 'initial approach letter' (appendix 1) to this member of staff. Once identified, this member of staff will be asked to e-mail an invitation letter (appendix 2) to each practice in their area that participates in the NHS DPP. This will usually be sent to the practice manager for onward distribution to GPs and nurses in their practice, however, if there are different approaches used in each area it may be sent directly to nominated GPs or nurses in each practice by the CCG lead.

If the CCG does not have a member of staff responsible for this programme then the R&D department will be asked to e-mail the invitation letter (appendix 2) directly to each practice that is involved in the referring patients to the NHS DPP.

The invitation letter (appendix 2) sent to practice managers will contain a copy of the participant information sheet (appendix 3) and a link to an electronic version of the questionnaire (appendix 4). Practice managers will be asked to forward this directly to GPs and nurses in their practice whom they feel would be in a position to answer the questionnaire e.g. diabetes lead GP or diabetic nurse. Individual practitioners who are interested will complete the online questionnaire by following the link. The questionnaires may be sent to multiple practitioners in each practice depending on size and specialist interest.

In order to improve response rates, a follow-up e-mail (appendix 5) will be sent to each of the CCG leads two weeks after confirmation has been received from them that the initial e-mail has been sent to practice managers. No further follow-up is planned after this time.

Participant recruitment – community pharmacists

In the CCGs identified above, the R&D department will be asked to e-mail an invitation letter (appendix 6), participant information sheet (appendix 3) and a link to an electronic version of the questionnaire (appendix 4) to all community pharmacies in their area. As above, this e-mail will be re-sent two weeks after as a follow-up to increase the response rate. Depending on the response rate, two weeks after the follow-up e-mail the research team will call the pharmacies in these areas using telephone number readily available on the NHS Choices website. If pharmacists have already completed the questionnaire then no further action will be taken and the participant thanked for their involvement. However, if they have not completed the questionnaire the research team will highlight the study to them and resend the information and questionnaire link to them. No further follow-up is planned after this point.

Sampling and sample size

In this study in order to gather data from practices with substantial experience of referring into the NHS DPP we will only recruit participants from the first 27 areas. Purposive sampling based on CCG deprivation scores and diabetes prevalence data will be used to select ten areas to target from the first wave sites with the aim to achieve an even spread across England. As an indication of the sample size available and on the assumption that we select the ten areas with the lowest number of practices and led by an NHS organisation, this will provide a potential recruitment sample of 1020 practices. With two potential practitioners in each practice (one GP and one nurse), this will yield a potential sample size of 2040 practitioners. Estimating a response rate of 10% (29) we expect a final sample size of 204 questionnaire responses. This will yield a confidence interval around a proportion of 10% of 5.9 – 14.1 which is deemed an appropriate range. Community pharmacists will be sampled using a convenience sample however the target for responses will be similar to that for the GPs and nurses, yielding a similar accuracy level.

Piloting

In order to pilot the questionnaire prior to distribution to the main sample, a small number of GPs, nurses and pharmacists from the previous qualitative work will be approached to provide feedback on the questions and topics covered. Any amendments to the questionnaire will be submitted to the ethics committee for approval.

Data collection procedures

Data collection will be undertaken using an electronic questionnaire (appendix 4) that will be distributed to eligible participants. The electronic questionnaire will be hosted online by JISC Online Surveys. This is the approved contractor for online surveys used by the University of East Anglia and conforms to GDPR requirements. The survey results will be accessible by the research team only via a password login.

The questionnaire will consist of five sections. The first section will gather participant demographics and current management of people with prediabetes. The second section will evaluate the existing NHS DPP using the APEASE criteria as described above. The third section will examine practitioners' views on the perceived role of community pharmacy in diabetes prevention. This section will be based on the outcomes from the completed

analysis of the previous phase of TK's PhD. It will also serve to triangulate the results from the previous phase. The fourth section will ask for any additional comments.

The questionnaire will take approximately 10 minutes as the majority of questions will consist of a Likert scale response from strongly agree to strongly disagree. It will be anonymous and consent will be confirmed by tick box on the first page of the questionnaire.

Incentives

In order to incentivise participation, at the end of the main questionnaire (section five) participants will be given the option of entering a prize draw to win a £50 voucher. Participants will be directed to a second questionnaire (appendix 7) to enter their details for entry into the prize draw. This information will not be linked to the first questionnaire and therefore responses will remain anonymous. A deadline for receipt of the questionnaires (and prize draw entries) will be set at 14th December 2018. After this point, participants will not be eligible for the prize draw and both the questionnaire links will be deactivated.

Ten entries into the prize draw will randomly be selected to receive a gift voucher of £50 using a random number generator. Successful participants will be e-mailed and asked to complete the relevant UEA form to facilitate payment.

Data analysis

Questionnaire data will be analysed quantitatively. A descriptive analysis of participants' demographics will be carried out using SPSS. Data will be explored to identify the distribution of respondents' experience and current experience of managing patients with prediabetes. Median (IQ) will be employed to examine how the NHS DPP is rated by practitioners using aspects of the APEASE criteria which include acceptability and practicability.

Similarly, we will employ appropriate statistical tests to examine practitioners' perceptions on feasibility of community pharmacy activity in the management of prediabetes. Responses to open ended sections of the questionnaire will be analysed using thematic analysis (30).

Ethics and Governance issues Data protection and anonymity

As stated previously, this project will use an electronic platform that is endorsed by the UEA and compliant with relevant data protection legislation. Responses to the main questionnaire will be anonymous and not linked to data collected as part of the prize draw. The data will only be accessed by the research team and stored on password protected computers at all times. Identifiable data relating to the prize draw will be downloaded onto the lead researcher's (MT) computer and the excel file will be password protected. It will only be viewed by the research team and will be accessed via a password protected computer. Once the prize draw has been completed and vouchers distributed, the data will be destroyed from all computers and the electronic platform.

Recruitment

The research team will approach potential participants twice in the case of GPs and nurses and up to three times for community pharmacists. We think that this is an appropriate number of times to contact potential participants to improve the response rate but not bombard NHS staff with repeated invitations.

Capacity and capability

It is anticipated that the CCG lead for the NHS DPP in each area will assess and confirm capacity and capability for the study. This will reduce workload for each of the practice managers and CCG R&D departments.

References

1. Diabetes UK. Diabetes Prevalence 2017.: Diabetes UK; 2017 [Available from: https://www.diabetes.org.uk/professionals/position-statementsreports/statistics/diabetes-prevalence-2017.
2. Hex N, Bartlett C, Wright D, Taylor M, Varley D. Estimating the current and future costs of Type 1 and Type 2 diabetes in the UK, including direct health costs and indirect societal and productivity costs. Diabet Med. 2012;29(7):855-62. 3.
National Cardiovascular Intelligence Network (NCVIN). NHS Diabetes Prevention Programme (NHS DPP) Non-diabetic hyperglycaemia. London: Public Health England 2015.
4. NICE. Type 2 diabetes: prevention in people at high risk. Public health guideline. In: Excellence NIfHaC, editor. 2012.
5. Li G, Zhang P, Wang J, Gregg EW, Yang W, Gong Q. The long-term effect of lifestyle interventions to prevent diabetes in the China Da Qing diabetes prevention study: a 20-year follow-up study. Lancet. 2008;371.
6. Ramachandran A, Snehalatha C, Mary S, Mukesh B, Bhaskar AD, Vijay V. The Indian Diabetes Prevention Programme shows that lifestyle modification and metformin prevent type 2 diabetes in Asian Indian subjects with impaired glucose tolerance (IDPP-1). Diabetologia. 2006;49(2):289-97.
7. Knowler WC, Barrett-Connor E, Fowler SE, Hamman RF, Lachin JM, Walker EA. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med. 2002;346.
8. Lindstrom J, Louheranta A, Mannelin M, Rastas M, Salminen V, Eriksson J, et al. The Finnish Diabetes Prevention Study (DPS): Lifestyle intervention and 3-year results on diet and physical activity. Diabetes Care. 2003;26.
9. Ali MK, Echouffo-Tcheugui J, Williamson DF. How effective were lifestyle interventions in real-world settings that were modeled on the diabetes prevention program? Health affairs. 2012;31.
10. Dunkley AJ, Bodicoat DH, Greaves CJ. Diabetes prevention in the real world: effectiveness of pragmatic lifestyle interventions for the prevention of type 2 diabetes and of the impact of adherence to guideline recommendations: a systematic review and meta-analysis. Diabetes Care. 2014;37.
11. Ashra NBS, R.; Carter, P.; Davies, M. J.; Dunkley, A. et.el. . A systematic review and meta-analysis assessing the effectiveness of pragmatic lifestyle interventions for the prevention of type 2 diabetes mellitus in routine practice London: Public Health England; 2015 [Available from: https://www.gov.uk/government/publications/diabetes-prevention-programmesevidence-review.
12. NHS England. NHS Diabetes Prevention Programme (NHS DPP) 2016 [Available from: https://www.england.nhs.uk/diabetes/diabetes-prevention/.

13. Finnish Diabetes Association. Programme for the prevention of type 2 diabetes in Finland 2003-2010. Finland; 2003.
14. Orozco LJ, Buchleitner AM, Gimenez-Perez G, Roque IFM, Richter B, Mauricio D. Exercise or exercise and diet for preventing type 2 diabetes mellitus. Cochrane Database Syst Rev. 2008(3):CD003054.
15. NHS England. Five Year Forward View 2014 [Available from: https://www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf.
16. Corlett SA, Krska J. Evaluation of NHS Health Checks provided by community pharmacies. J Public Health (Oxf). 2015.

17. Public Health England. Consolidating and developing the evidence base and research for community pharmacy's contribution to publuc health: a progress report from Task Group 3 of the Pharmacy and Public Health Forum. London: Public Health England 2014.
18. Twigg MJ, Wright DJ, Thornley T, Haynes L. Community pharmacy type 2 diabetes risk assessment: demographics and risk results. Int J Pharm Practice. 2015;23(1):80-2.
19. Kullgren JT, Knaus M, Jenkins KR, Heisler M. Mixed methods study of engagement in behaviors to prevent type 2 diabetes among employees with prediabetes. BMJ Open Diabetes Research & Care. 2016;4(1).
20. Laws RA, Fanaian M, Jayasinghe UW, McKenzie S, Passey M, Davies GP, et al. Factors influencing participation in a vascular disease prevention lifestyle program among participants in a cluster randomized trial. BMC Health Serv Res. 2013;13:201.
21. Penn L, Moffatt SM, White M. Participants' perspective on maintaining behaviour change: a qualitative study within the European Diabetes Prevention Study. BMC Public Health. 2008;8.
22. Aziz Z, Absetz P, Oldroyd J, Pronk NP, Oldenburg B. A systematic review of real-world diabetes prevention programs: learnings from the last 15 years. Implementation Science. 2015;10(1):172.
23. Whittemore R. A systematic review of the translational research on the Diabetes Prevention Program. Translational behavioral medicine. 2011;1(3):480-91.
24. Public Health England. Pharmacy: A way forward for public health. London: Public Health England; 2017.
25. PSNC PV, Royal Pharmaceutical Society Community Pharmacy Forward View. 2016.
26. Michie S. AL, West R. . The Behaviour Change Wheel: A Guide to Designing Interventions 1st ed. London: Silverback; 2014.
27. West R, Michie S. Applying the Becaviour Chanhe Wheel - A very brief guide 2015 [Available from: https://www.ucl.ac.uk/behaviour-change/files/bcwsummary.pdf.

28. Bowling A. Research Methods in Health 4th ed. Maidenhead: Open University Press; 2014.
29. Bonevski B, Magin P, Horton G, Foster M, Girgis A. Response rates in GP surveys - trialling two recruitment strategies. Australian family physician. 2011;40(6):427-30.
30. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol. 2006;3(2):77-101.

Appendix 5.2

Ethics approval for the questionnaire study (Chapter 5)

Appendix 5.2: HRA ethics approval

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Mr Ceyhan Enver-Osman
School of Pharmacy
University of East Anglia
Norwich
NR47TJ

04 October 2018

Dear Mr Enver-Osman

HRA and Health and Care

Study title:	**The potential involvement of community pharmacies in diabetes prevention: questionnaire Study**
IRAS project ID:	**252420**
Protocol number:	**1**
Sponsor	**University of East Anglia**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

How should I continue to work with participating NHS organisations in England and Wales? You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Participating NHS organisations in England and Wales **will not** be required to formally confirm capacity and capability before you may commence research activity at site. As such, you may commence the research at each organisation 35 days following sponsor provision to the site of the local information pack, so long as:

- You have contacted participating NHS organisations (see below for details)

- The NHS organisation has not provided a reason as to why they cannot participate
- The NHS organisation has not requested additional time to confirm.

You may start the research prior to the above deadline if the site positively confirms that the research may proceed.

If not already done so, you should now provide the local information pack for your study to your participating NHS organisations. A current list of R&D contacts is accessible at the NHS RD Forum website and these contacts MUST be used for this purpose. After entering your IRAS ID you will be able to access a password protected document (password: **House45**). The password is updated on a monthly basis so please obtain the relevant contact information as soon as possible; please do not hesitate to contact me should you encounter any issues.

Commencing research activities at any NHS organisation before providing them with the full local information pack and allowing them the agreed duration to opt-out, or to request additional time (unless you have received from their R&D department notification that you may commence), is a breach of the terms of HRA and HCRW Approval. Further information is provided in the "*summary of assessment*" section towards the end of this document.

It is important that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed here.

I am a participating NHS organisation in England or Wales. What should I do once I receive this letter?

You should work with the applicant and sponsor to complete any outstanding arrangements so you are able to confirm capacity and capability in line with the information provided in this letter.

The sponsor contact for this application is as follows:

Name: Ms Maya Kumar

Tel: 01603592994

E-mail: maya.kumar@uea.ac.uk

Who should I contact for further information?

Please do not hesitate to contact me for assistance with this application. My contact details are below. Your IRAS project ID is **252420**. Please quote this on all correspondence.

Yours sincerely

Kevin Ahmed, Assessor

Telephone: 0207 104 8171

E-mail: hra.approval@nhs.net

Copy to: Ms Maya Kumar, Sponsor Contact, University of East Anglia

Dr Marie Girdham, R@&D Contact, NHS East Riding of Yorkshire CCG

Appendix 5.3

Ethics amendment approvals for questionnaire study

Appendix 5.3: HRA approval for amendment

Amendment Categorisation and Implementation Information

Dear Dr Twigg,

IRAS Project ID:	252420
Short Study Title:	Community pharmacy's role in diabetes prevention
Date complete amendment submission received:	17 October 2018
Amendment No./ Sponsor Ref:	1
Amendment Date:	17 October 2018
Amendment Type:	Non-substantial
Outcome of HRA and HCRW Assessment	**This e-mail also constitutes HRA and HCRW Approval for the amendment,** and you should not expect anything further.
For NHS/HSC R&D Office information	
Amendment Category	**C**

Thank you for submitting an amendment to your project. We have now categorised your amendment and please find this, as well as other relevant information, in the table above.

When can I implement this amendment?

You may implement this amendment **immediately**. Please note that you may only implement changes described in the amendment notice. Please do not hesitate to contact me if you require further information.

Kind regards

Kevin Ahmed

Amendment 5.3 FMH approval

Faculty of Medicine and Health Sciences Research Ethics Committee

University of East Anglia

Research & Innovation Services
Floor 1, The Registry
University of East Anglia
Norwich Research Park
Norwich, NR4 7TJ

Email: fmh.ethics@uea.ac.uk

Web: www.uea.ac.uk/researchandenterprise

Michael Twigg
(PHA)

25 October 2018

Dear Michael

Project Title: The potential involvement of community pharmacies in diabetes prevention Reference: 2017/18 - 148

Thank you for your e-mail notifying us of the amendments you would like to make to your above proposal. These have been considered and we can now confirm that your amendments have been approved. Please can you ensure that any further amendments to either the protocol or documents submitted are notified to us in advance, and also that any adverse events which occur during your project are reported to the Committee.

Approval by the FMH Research Committee should not be taken as evidence that your study is compliant with GDPR and the Data Protection Act 2018. If you need guidance on how to make your study GDPR compliant, please contact your institution's Data Protection Officer.

Please can you also arrange to send us a report once your project is completed.

Yours sincerely,

Professor M J Wilkinson
Chair
FMH Research Ethics Committee

Appendix 5.4

Initial approach e-mail to CCG leads for the NHS DPP

Appendix 5.4: Initial approach e-mail to CCG leads for the NHS DPP

University of East Anglia

Subject: The potential role of community pharmacies in diabetes prevention

Dear Sir/Madam,

We are five fourth year pharmacy students at the School of Pharmacy, University of East Anglia. We are in the process of conducting our final year research project, working alongside a PhD student and our academic supervisors. Our project aims to obtain feedback from GPs and nurses that are currently referring patients to the NHS Diabetes Prevention Programme (DPP) as well as obtain their opinion as to the role of community pharmacies in diabetes prevention.

We would be very interested in GP and nurse views regarding the implementation of the DPP in your CCG(s). We would be grateful if you could send the attached e-mail and information sheet to each practice within your area which participates in the NHS DPP process.

If you have any questions, please do not hesitate to contact us through the e-mail addresses provided below.
Thank you for your time and we look forward to hearing from you soon.

Kind regards,
Sekander Amini; s.amini@uea.ac.uk
Ceyhan Enver-Osman; c.enver-osman@uea.ac.uk
Achilleas Riniotis; a.riniotis@uea.ac.uk
Zyhar Said; z.said@uea.ac.uk
Olipa Zulu; o.zulu@uea.ac.uk

Project supervisors: Miss Thando Katangwe and Dr Michael Twigg, m.twigg@uea.ac.uk

Appendix 5.5

E-mail to practice managers participating in the NHS DPP

Appendix 5.5: E-mail to practice managers participating in the NHS DPP

University of East Anglia

Subject: The potential role of community pharmacies in diabetes prevention

Dear Sir/Madam,

We are five fourth year pharmacy students at the School of Pharmacy, University of East Anglia. We are in the process of conducting our final year research project, working alongside a PhD student and our academic supervisors. Our project aims to obtain feedback from GPs and nurses that are currently referring patients to the NHS Diabetes Prevention Programme (DPP) as well as obtain their opinion as to the role of community pharmacies in diabetes prevention.

We would be very interested in GP and nurse views regarding referral of patients to the NHS DPP in your practices. We would be grateful if you could forward this e-mail to each GP and nurse within your practice who has an interest in diabetes management or is responsible for referrals to the NHS DPP. The questionnaire should take no longer than 10 minutes to complete and is completely anonymous.

The attached participant information sheet contains more information about the project and what it involves. As a thank you for participating, there is a chance to win one of ten £50 vouchers by entering a prize draw at the end of the questionnaire.

If you are happy to complete our questionnaire, please click on the link below:

(INSERT LINK)

If you have any questions, please do not hesitate to contact us through the e-mail addresses provided below.

Thank you for your time and we look forward to hearing from you soon.
Kind regards,
Sekander Amini; s.amini@uea.ac.uk
Ceyhan Enver-Osman; c.enver-osman@uea.ac.uk
Achilleas Riniotis; a.riniotis@uea.ac.uk
Zyhar Said; z.said@uea.ac.uk
Olipa Zulu; o.zulu@uea.ac.uk
Project supervisors: Miss Thando Katangwe and Dr Michael Twigg, m.twigg@uea.ac.uk

Appendix 5.6

Participant Information Sheet

Appendix 5.6: Participant Information Sheet

University of East Anglia

The potential role of community pharmacies in diabetes prevention: Questionnaire Study

Participant Information Sheet

We would like to invite you to take part in our final year research project. This information sheet will provide you with details about the aims of the project as well as what we will ask of you. Please take your time to read the following information. If you have any questions, or would like more information, please feel free to contact us.

What is the purpose of this research project?

The NHS Diabetes Prevention Programme was launched in 2016 to tackle the growing problem of diabetes in the UK (more information can be found at: https://www.england.nhs.uk/diabetes/diabetes-prevention/. We believe that community pharmacy may be able to assist in the prevention of type 2 diabetes however there is little evidence to suggest what this role should involve and how it integrates with the primary care team.

After conducting interviews and focus groups with GPs, nurses, pharmacists and commissioners in early 2018 we now have a better understanding of the benefits and challenges of referring patients to the NHS DPP and the role that community pharmacy might play in any future implementation of the programme. However, this was undertaken with a small number of practitioners and so there is a need to confirm these findings in a larger sample before making any judgements regarding the role of the community pharmacy.

Why have I been invited?

You have been invited as you are either:

- a GP or nurse in practice that refers patients to the NHS DPP or
- a community pharmacist practicing in an area where the NHS DPP is operational.

Do I have to take part?

No, your participation is voluntary. If you choose to complete the questionnaire we will assume you have given your consent to participate and for your data to be used in the analysis. This will be confirmed by ticking a box on the first page of the questionnaire.
At the end of the questionnaire there will be an option to enter a prize draw to win one of ten £50 vouchers as a thank you for participating. If you want to be entered into the draw then you need to click the link to complete a separate questionnaire so that we have your contact details. This ensures that your contact details are separate from the main questionnaire answers and maintains anonymity. If you are successful we will then contact you using the information provided. The deadline for receipt of the information for the

completed questionnaire and prize draw information is 14th December 2018. Entries received after this time will not be included in the analysis or the prize draw.

What does the project involve for me?
We have sent you a link to an electronic questionnaire [INSERT LINK]. This will take approximately 10 minutes to complete. It will be sent back to us online and will be anonymous. For GPs and nurses, the questionnaire will focus on the NHS DPP and the role of community pharmacy in diabetes prevention. For pharmacists, the questionnaire will just focus on the latter.

If you decide to stop completing the questionnaire at any point the information you have already entered will be used for analysis. It will not be possible to return to the questionnaire to complete your answers at a later date.

What will you do with my information?
We will be using the data obtained to produce our research project and our results will be presented to our peers at the University of East Anglia in January 2019. If requested a summary report can also be sent to your practise after our final presentation. Please indicate this on the second questionnaire.

Will my information be confidential?
Yes. All study involvement will remain strictly confidential and all data will be kept on a password protected computer and accessed by the research team only. The online survey platform used for this study has been approved by the UEA and complies with the General Data Protection Regulations.

The University of East Anglia is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of East Anglia will keep identifiable information about you until the prize draw has been made, after which the information will be destroyed.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information
https://portal.uea.ac.uk/information-services/strategy-planning-and-compliance/regulations-and-policies/information-regulations-and-policies/data-protection/privacy-notices

Complaints and further contact

If you have any further questions about this study or any of the information given above please do not hesitate to contact us on the e-mail addresses below and we will be happy to answer any questions you may have. If you have any concerns or complaints about the research then please contact the Head of School, Prof Mark Searcey (m.searcey@uea.ac.uk).

Contact details:
Research Team: Sekander Amini; s.amini@uea.ac.uk
Ceyhan Enver-Osman; c.enver-osman@uea.ac.uk
Achilleas Riniotis; a.riniotis@uea.ac.uk
Zyhar Said; z.said@uea.ac.uk
Olipa Zulu; o.zulu@uea.ac.uk

Project supervisor: Dr Michael Twigg
Lecturer in Primary Care Pharmacy, School of Pharmacy,
University of East Anglia,
Norwich,
E-mail: m.twigg@uea.ac.uk
Telephone number: 01603 592015

Appendix 5.7

Questionnaire

Appendix 5.7: Questionnaire

University of East Anglia

The potential role of community pharmacies in diabetes prevention
Introduction

Thank you for taking time to participate in this study. We aim to explore the role of community pharmacy in diabetes prevention. This questionnaire will take no more than 10 minutes to complete. Your responses to this questionnaire will remain anonymous

1. Do you consent to participate in this study? Yes No

Part 1: Demographics
This section aims to obtain information about your practice. Please tick the answer that applies to you.

2. What is your age?
3. What is your gender? Male Female Other Prefer not to say
4. How many years have you been working in your current role?
5. I am a GP Nurse Pharmacist

If GP/nurse the form will move to Q6. If pharmacist then form will move to Q12

6. Please state your approximate practice size
7. How many GPs and nurses work in your practice? GPs:
   Nurses:
8. Do you have a specialist interest in diabetes? Yes No
9. Are you a dispensing practice? Yes No
10. Is your practice co-located with a community pharmacy? Yes No
11. Does your practice open for longer hours e.g. in the evenings and weekends? Yes No
    How do you currently manage pre-diabetes in your practice?
    Refer to the NHS DPP
    Diet and lifestyle advice (face to face)
    Diet and lifestyle advice (written information)
    Signpost to online resources
    Other:

The form will now move to Q18

12.	Please state how many prescription items you dispense per month on average		
13.	Do you have a consultation room?	Yes	No
14.	Do you have an accredited checking technician (ACT)?	Yes	No
15.	If yes to the previous question, does the ACT routinely check dispensed medicines in your pharmacy?	Yes	No
16.	Do you provide any locally commissioned services?	Yes	No
17.	If yes to 14, please state what services you provide.		

The form will now move to Q24

Part 2: Current NHS DPP

This section aims to find out the practitioner view on the functionality of the current Diabetes Prevention Programme using a set of criteria (APEASE).
Please tick the appropriate box.

	APPEASE Criteria	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
18.	The programme is an acceptable service for these patients.	5	4	3	2	1
19.	Referring patients to the programme is easy for me	5	4	3	2	1
20.	This programme is good use of NHS money	5	4	3	2	1
21.	There are adequate funds to continue delivering the service in the future	5	4	3	2	1
22.	The DPP has not had any unwanted/unintentional consequences	5	4	3	2	1
23.	This programme does not disadvantage any groups of people	5	4	3	2	1

Part 3: Community pharmacy's role in diabetes prevention

This section aims to investigate the potential role for community pharmacy in diabetes prevention.

		Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
24.	GPs and nurses have adequate knowledge of services provided in community pharmacy	5	4	3	2	1
25.	Community pharmacy teams would need the additional training to	5	4	3	2	1

	deliver diabetes prevention services					
26.	Once trained, community pharmacy teams would be capable of delivering pre-diabetes screening services	5	4	3	2	1
27.	Once trained, community pharmacy teams would be capable of delivering one-off diet and lifestyle advice for people with pre-diabetes following screening	5	4	3	2	1
28.	Once trained, community pharmacy teams would be capable of delivering on-going diet and lifestyle advice for people with pre-diabetes following screening	5	4	3	2	1
29.	The community pharmacy is an accessible setting for delivering diabetes prevention services	5	4	3	2	1
30.	Diabetes prevention services in this setting would likely have shorter waiting times than the NHS DPP	5	4	3	2	1
31.	Community pharmacy teams could create time to deliver diabetes prevention services	5	4	3	2	1
32.	Consultation rooms in community pharmacies are adequate for delivering services	5	4	3	2	1
33.	Community pharmacy would need extra funding and resources to deliver diabetes prevention services	5	4	3	2	1
34.	Community pharmacy has adequate access to patient records to facilitate the delivery of diabetes prevention services	5	4	3	2	1

35.	Current IT systems are sufficient for communication and feedback with general practice	5	4	3	2	1
36.	Community pharmacy diabetes prevention services should be integrated with general practice	5	4	3	2	1
37.	Community pharmacy diabetes prevention services would need referral from general practice	5	4	3	2	1
38.	GP practices would need to be reimbursed appropriately for referring patients to diabetes prevention services in community pharmacy and acting on their feedback	5	4	3	2	1
39.	Diabetes prevention services in this setting would need to be promoted to both patients and practitioners	5	4	3	2	1
40.	Community pharmacy is an acceptable setting for the delivery of diabetes prevention services for people unable to engage with the NHS DPP	5	4	3	2	1
41.	It is feasible to implement diabetes prevention services in community pharmacy	5	4	3	2	1
42.	Community pharmacy teams could be trusted to deliver diabetes prevention services properly	5	4	3	2	1
43.	Successful delivery of diabetes prevention services in community pharmacy depends on positive relationships with general practices	5	4	3	2	1

44.	Any new service in community pharmacy should minimise additional workload for general practice	5	4	3	2	1

Part 4: Additional comments
If you have any additional comments on the NHS DPP or the community pharmacy role in diabetes prevention then please type these in the box below.

Part 5: Prize draw and summary report request
Please follow this link: [insert link] to enter the prize draw and/or request a copy of the final summary report.

Appendix 5.8

Follow-up e-mail to practice managers participating in the NHS DPP

Subject: The potential role of community pharmacies in diabetes prevention

Dear Sir/Madam,

If you have already completed this questionnaire then please ignore this e-mail. Thank you for taking part in our study. We are five fourth year pharmacy students at the School of Pharmacy, University of East Anglia. We are in the process of conducting our final year research project, working alongside a PhD student and our academic supervisors. Our project aims to obtain feedback from GPs and nurses that are currently referring patients to the NHS Diabetes Prevention Programme (DPP) as well as obtain their opinion as to the role of community pharmacies in diabetes prevention.

We would be very interested in GP and nurse views regarding referral of patients to the NHS DPP in your practices. We would be grateful if you could forward this e-mail to each GP and nurse within your practice who has an interest in diabetes management or is responsible for referrals to the NHS DPP. The questionnaire should take no longer than 10 minutes to complete and is completely anonymous.

The attached participant information sheet contains more information about the project and what it involves. As a thank you for participating, there is a chance to win one of ten £50 vouchers by entering a prize draw at the end of the questionnaire.

If you are happy to complete our questionnaire, please click on the link below:
(INSERT LINK)

If you have any questions, please do not hesitate to contact us through the e-mail addresses provided below.

Thank you for your time and we look forward to hearing from you soon.
Kind regards,
Sekander Amini; s.amini@uea.ac.uk
Ceyhan Enver-Osman; c.enver-osman@uea.ac.uk
Achilleas Riniotis; a.riniotis@uea.ac.uk
Zyhar Said; z.said@uea.ac.uk
Olipa Zulu; o.zulu@uea.ac.uk
Project supervisors: Miss Thando Katangwe and Dr Michael Twigg, m.twigg@uea.ac.uk

Appendix 5.9

E-mail to community pharmacists

Appendix 5.9: E-mail to community pharmacists

Subject: The potential role of community pharmacies in diabetes prevention

Dear Sir/Madam,

We are five fourth year pharmacy students at the School of Pharmacy, University of East Anglia. We are in the process of conducting our final year research project, working alongside a PhD student and our academic supervisors. Our project aims to obtain opinions from community pharmacists on whether there is a role for them in supporting the NHS Diabetes Prevention Programme (NHS DPP).

We have already conducted interviews and focus groups with various professionals involved in diabetes prevention and community pharmacy. This questionnaire seeks to confirm these findings in a larger groups of practitioners. The questionnaire should take no longer than 10 minutes to complete and is completely anonymous.

The attached participant information sheet contains more information about the project and what it involves. As a thank you for participating, there is a chance to win one of ten £50 vouchers by entering a prize draw at the end of the questionnaire.

If you are happy to complete our questionnaire, please click on the link below:

(INSERT LINK)
If you have any questions, please do not hesitate to contact us through the e-mail addresses provided below.

Thank you for your time and we look forward to hearing from you soon.
Kind regards,
Sekander Amini; s.amini@uea.ac.uk
Ceyhan Enver-Osman; c.enver-osman@uea.ac.uk
Achilleas Riniotis; a.riniotis@uea.ac.uk
Zyhar Said; z.said@uea.ac.uk
Olipa Zulu; o.zulu@uea.ac.uk

Project supervisors: Miss Thando Katangwe and Dr Michael Twigg, m.twigg@uea.ac.uk

Appendix 5.10

Prize draw and summary report questionnaire

Appendix 5.10: Prize draw and summary report questionnaire

University of East Anglia

The potential role of community pharmacies in diabetes prevention

Entry for the prize draw and summary report

Thank you for taking time to participate in this study. As a thank you for participating there is a chance to win a £50 voucher. There are ten vouchers available. Only one entry per person will be counted.

Please enter your details below to be eligible for the draw. Entries must be made before the 14th December 2018. There is also an opportunity to state whether you would like to see a copy of a summary report that is produced as a result of the data analysis.

(All answers compulsory)

1. Please enter your name
2. Please enter your e-mail address
3. Please enter your postal address (please note, this is where the voucher will be sent if you are successful in the prize draw).

4. Do you wish to be included in the prize draw?	Yes	No
5. Do you wish to receive a copy of the final summary report?	Yes	No
6. How would you like to receive this report?	E-mail	Post

Thank you for completing both questionnaires

Appendix 6.1

Nominal group technique questionnaire

Appendix 6.1: Nominal group technique questionnaire (people with NDH)

University of East Anglia

Thank you for agreeing to participate in the focus group study. This survey aims to introduce topics that will be discussed on the day. Please note your responses for each section as this will constitute the discussion. This questionnaire will take no more than 5-10 minutes to complete and your responses will remain anonymous.

1. Do you consent to participate in this study? ***Required***

- Yes
- No

2. What is or was your level of participation in the Healthier You NHS Diabetes Prevention Programme? ***Required***

- Waiting for an initial assessment
- Attending
- Completed
- Dropped out
- Declined

Community pharmacy: target services and uptake

7. Which diabetes prevention service(s) should be provided in community pharmacy? ***Required***

- [ ] Pre-diabetes screening only, with referral onto general practice for further confirmatory tests
- [ ] Pre-diabetes screening only, with referral onto the group based NHS Diabetes Prevention Programme
- [ ] Alternative one to one diabetes prevention services including screening and lifestyle advice
- [ ] Follow-up monitoring services after the NHS Diabetes Prevention Programme (to monitor weight, blood pressure, blood sugars & cholesterol)
- [ ] Private screening and monitoring services

8. Which **ONE** of the following factors could **encourage people with pre-diabetes to engage** with community pharmacy-based diabetes prevention services? ***Required***

- ○ Being aware that the services are available in community pharmacies
- ○ Knowing that community pharmacy is an appropriate place to access the service
- ○ Having a recommendation from a GP or nurse
- ○ Making sure that the service is provided in collaboration with general practice
- ○ Having received a good service previously from community pharmacy
- ○ Having the assurance that the service will be private and confidential

Delivering community pharmacy services

9. Which **ONE** of the following **could most likely increase capability** of community pharmacy teams to deliver diabetes prevention services? ***Required***

- Having the practical skills to deliver the services e.g. measuring blood sugars
- Having enough knowledge about pre-diabetes and how it is managed
- Having good communication skills
- Having enough experience with delivering the service

10. Please select **ONE** factor that could **likely encourage** community pharmacy teams to deliver diabetes prevention services? ***Required***

- Having enough staff to deliver the services
- Having self-confidence to deliver the services (enhanced by training)
- Having the whole pharmacy team involved in delivering the service i.e. including healthcare assistants and dispensers
- Having an appointment system to manage delivery of the services
- Having the support of general practices
- Having the confidence to communicate findings to general practices

11. Please select **ONE factor** that is most likely to increase the chances of community pharmacy to deliver diabetes prevention services ***Required***

- Having suitable consulting rooms and facilities
- Having enough access to patient medical records
- Having enough staff to deliver the service
- Having good IT facilities to enable referrals and feedback with general practice

12. Which **ONE** of the following is **important for delivering** community pharmacy diabetes prevention services in partnership with other healthcare services? *Required*

- It is important to show that the services are producing positive health benefits for people with pre-diabetes e.g. lowering blood sugars
- It is important not create additional work for general practices
- It is important to reduce general practice workload
- It is important not to create any financial competition with general practice
- It is important that the services should not affect prescription services

13. Which ONE set of statements from the above sections wold mostly determine the successful delivery of diabetes prevention services in community pharmacy? ***Required***

- Your answer to 9
- Your answer to 10
- Your answer to 11
- Your answer to 12

Appendix 6.1: Nominal group technique questionnaire (commissioners, community pharmacy and general practice personnel)

University of East Anglia

Focus group topics: Community pharmacy-based diabetes prevention services

Thank you for agreeing to participate in the focus group study. This survey aims to introduce topics that will be discussed on the day. Please note your responses for each section as this will constitute the discussion. This questionnaire will take no more than 5-10 minutes to complete and your responses will remain anonymous.

Do you consent to participate in this study? ***Required***

- Yes
- No

I am a ***Required***

- Pharmacist
- Pharmacy technician
- Dispenser
- General practitioner
- Nurse
- Health care assistant
- Commissioning representative

How long have you worked in your current role? *Required*

Target services and uptake

Which **diabetes prevention services** should be provided in community pharmacy? *Required*

- [ ] Pre-diabetes screening only (fasting plasma glucose), with referral onto general practice for further HbA1c screening
- [ ] Pre-diabetes screening only (HbA1c), with referral onto the group based NHS diabetes prevention programme
- [ ] Alternative one to one diabetes prevention services including screening and lifestyle advice
- [ ] Follow-up monitoring services after the NHS diabetes prevention programme (to monitor BMI, BP, HbA1c & cholesterol)
- [ ] Private screening and monitoring services

Which **ONE** of the following could **encourage people with pre-diabetes to engage** with community pharmacy-based prevention services? ***Required***

- ○ Being aware that the services are available in community pharmacies
- ○ Knowing that community pharmacy is an appropriate place to access the service
- ○ Having a recommendation from a GP or nurse
- ○ Making sure that the service is provided in collaboration with general practice
- ○ Having received a good service previously from community pharmacy
- ○ Having the assurance that the service will be private and confidential

Service implementation

Which **ONE** of the following would **most likely increase the capability** of community pharmacy teams to deliver diabetes prevention services? ***Required***

- Having technical skills to deliver the services e.g. obtaining a blood sample 1a
- Having enough knowledge of pre-diabetes and its management 1b
- Having good consultation skills 1c
- Having regular engagement with people with pre-diabetes to maintain knowledge and skills 2b

Financial incentives are a key factor that could increase motivation to deliver diabetes prevention services. Please select **ONE** additional factor that would **most likely motivate** community pharmacy teams to deliver such services? ***Required***

- Having enough staff to deliver the service
- Having self-confidence to deliver the services (enhanced by training and experience)
- Having the whole pharmacy team involved in delivering the service i.e. including healthcare assistants and technicians
- Having a structured working pattern to manage delivery of the service e.g. appointment systems
- Having the support of general practices
- Having the confidence to communicate findings to general practices

Time and funding are key factors needed to deliver diabetes prevention services. **Please select ONE additional factor** most likely to increase the opportunity to deliver such services. *Required*

- Having suitable consulting rooms and facilities
- Having adequate access to patient medical records
- Having enough staff to deliver the service

- Having adequate IT facilities to enable referrals and feedback with general practice

Which **ONE** of the following is **important for the implementation** of community pharmacy diabetes prevention services **as part of primary care**? *Required*

- It is important to demonstrate impact by reporting patient outcomes
- It is important not to create additional work for general practices
- It is important to reduce general practice workload
- It is important not to create any financial competition with general practice
- It is important that other primary care providers are reassured that the service would not affect prescription services

Which of the points that you have ticked above do you think is most important to address overall: *Required*

- Your answer to Q3
- Your answer to Q4
- Your answer to Q5
- Your answer to Q6