Keele University

PROTOCOL

Version 2.0 dated 5th November 2018

- **This protocol has regard for the HRA guidance and order of content**

RESEARCH REFERENCE NUMBERS

IRAS Number: 248316

Sponsor Number: RG-0275-18

ISRCTN Number: ISRCTN82531292

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol, GCP guidelines, the Sponsor's SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Signature: ..... Date: 05/11/2018

Name: ……Professor Christian D Mallen……..

LIST OF CONTENTS

LIST OF ABBREVIATIONS

CCG	Clinical Commissioning Group
CI	Chief Investigator
CRN: WM	NIHR Clinical Research Network: West Midlands
EMIS	Egton Medical Information Systems
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GPSoC	General Practice System of Choice
HCP	Health Care Professional
ONS	Office for National Statistics
PI	Principal Investigator
PIC	Participant Identification Centre
PIL	Participant Information Leaflet
QOF	Quality Outcomes Framework
REC	Research Ethics Committee
RUG	Research User Group
SAP	Statistical Analysis Plan
SMF	Study Master File
SMG	Study Management Group
SNOMED	Systematized Nomenclature of Medicine - Clinical Terms
SOP	Standard Operating Procedure
TECS	Technology Enabled Care Services

KEY STUDY CONTACTS

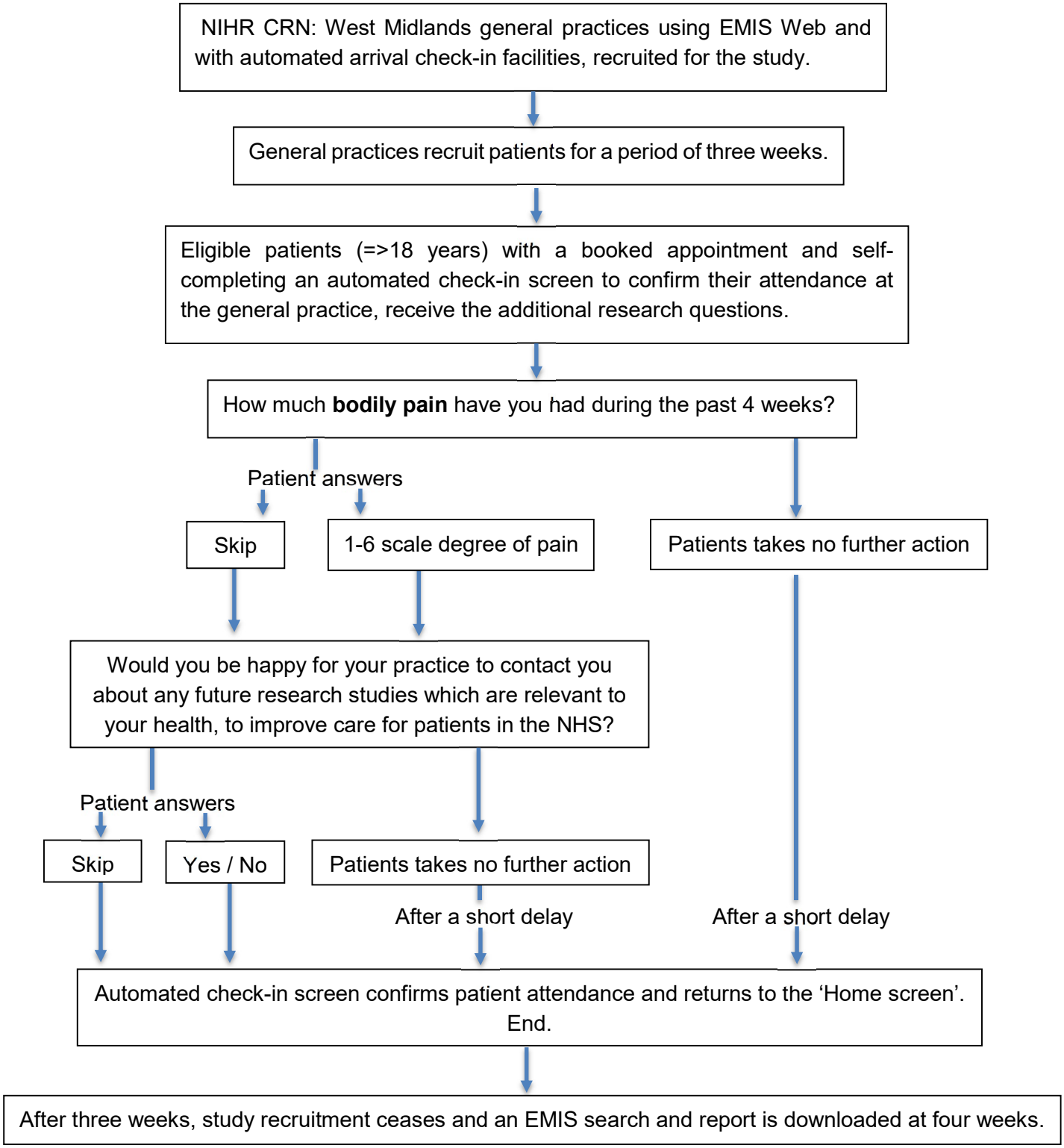
Chief Investigator	Professor Christian Mallen Arthritis Research UK Primary Care Centre Research Institute for Primary Care & Health Sciences Keele University, Staffordshire, ST5 5BG Tel: 01782 734879 c.d.mallen@keele.ac.uk
Principal Investigator	Sarah Lawton Arthritis Research UK Primary Care Centre Research Institute for Primary Care & Health Sciences Keele University, Staffordshire, ST5 5BG Tel: 01782 734887 s.a.lawton@keele.ac.uk
Sponsor	Dr Clark Crawford Head of Research Integrity, Directorate of Engagement & Partnerships, Innovation Centre 2, Keele University, Staffordshire, ST5 5NH 01782 733371 research.governance@keele.ac.uk
Funder	Professor Christian Mallen: NIHR Research Professorship (NIHR-RP-2014-04-026)
Study Management	Arthritis Research UK Primary Care Centre Research Institute for Primary Care & Health Sciences Keele University, Staffordshire, ST5 5BG 01782 734887 s.a.lawton@keele.ac.uk
Lead Statistician	Dr Sara Muller Senior Research Fellow: Epidemiology and Applied Statistics Arthritis Research UK Primary Care Centre Research Institute for Primary Care & Health Sciences Keele University, Staffordshire, ST5 5BG Tel: 01782 734842 s.muller@keele.ac.uk
Key Protocol Contributors	- Dr Toby Helliwell, GP Partner & NIHR Academic Clinical Lecturer in General Practice - Simon Wathall, Health Informatics Specialist Arthritis Research UK Primary Care Centre Research Institute for Primary Care & Health Sciences Keele University, Staffordshire, ST5 5BG Tel: 01782 734887

STUDY SUMMARY

Study title	**A**utomated **C**heck-in **D**ata **C**ollection Study	
Internal ref. number (or short title)	AC DC STUDY	
Study design	Pilot feasibility	
Study participants	Patients consulting in general practice, completing an automated check-in screen prior to their consultation.	
Planned sample size	Approximately n=1166 per participating general practice (depending on practice list size and number of consulting clinicians during recruitment period). Total sample size n=9604, ~11 general practices	
Planned recruitment period	3 weeks in each participating general practice.	
	Objectives	**Outcome measures**
Primary	To assess patient acceptability of answering two research questions in the general practice waiting room using an automated check-in screen.	Percentage of completed automated check-in screens with entered research data.

STUDY FLOW CHART

Flow chart demonstrating recruitment of participants into the study.



1 BACKGROUND

Instead of patients needing to speak to the receptionist, it has now become commonplace for general practice waiting rooms to host an automated check-in screen. Practice waiting rooms typically display a notice, directing patients arriving for a booked appointment, to self-check-in. In a time where primary care is underfunded[1], self-check-in is a cost effective process which frees up receptionist time for other tasks[2]. Whilst this automated process provides an efficient solution to the completion of a practice administrative function, it may also be possible to quickly collect additional information about the consulting patient. There is little evidence available in the literature to describe the use of automated check-in screens for the collection of additional patient data and therefore an assessment of patient acceptability for providing additional information for the purposes of research, whilst self-completing an automated check-in screen is to be piloted.

In order to support the delivery of health and social care, the role of technology enabled care services (TECS) are gaining increasing recognition[3]. We can provide parallels in how people have converted to using technology in their everyday lives, for example in banking, shopping and communications, with how people receive delivery of health and social care[4]. The use of TECS support the transformation of new models of care delivery and allow patients to meet their needs and preferences, together with the provision of efficiencies for general practice. Improving digital literacy across the health and social care landscape needs to be embedded in organisations and individuals[5]. An automated check-in screen which displays additional health related questions is also one way of providing patients with the ability to take control of their choices and how their personal data are managed.

The EU General Data Protection Regulation (GDPR) replaced the Data Protection Directive 95/46/EC on 25th May 2018. As part of this new regulation there is the right of the data subject to obtain from the data controller, confirmation as to whether or not personal data concerning them is being processed, where and for what purpose[6]. General practices are data controllers, of patients' (data subjects) healthcare data. This new legislation allows data subjects to have control over how their data is processed by the controller. The invitation to participate in healthcare research and the percentage conversion rate into participants recruited is variable, with many comprehensible and confounding factors affecting recruitment success rates. Collecting data on whether patients are happy to be contacted about research would provide general practices with efficiencies in resource, improved accuracy in sampling and provide patients with more control of how their data are used.

Increasingly, patients are living with multiple, long-term chronic conditions, both physical and psychological - and at the same time general practitioners are being asked to do more routine health checks, ask more questions and give more advice as standard during consultations. The standard 10-minute appointment is simply inadequate to deal with this[7]. Pain is commonly neglected by patients and not prioritised by general practitioners. Although effective pain management interventions and

programmes exist, provision of these services is inconsistent, and chronic pain is not given the priority it requires in view of the extent of its burden on individuals and society[8]. There being a prompt for patients to complete at checking in for a booked consultation at the general practice, with regards to the patient's recent experiences of pain, might then encourage them to highlight this in a consultation. This data collected can additionally be entered straight into the patient's medical record and can facilitate the impending consultation, making an efficient use of the 10-minute consultation.

The electronic Clinical Record Management system which each general practice uses, is dictated by their local Clinical Commissioning Group (CCG). The general practice systems of choice (GPSoC) are EMIS Health, TPP SystmOne, Vision, and Microtest Health. These systems are used by 56%, 36%, 7% and 1% respectively, of general practices within England[9]. These GPSoC are now designed to include optional extras for general practices; patients can be provided with information, provide feedback for service evaluation and book future appointments using the interoperability functions of these sytems[10]. Some have a questionnaire module, which can be used to gain responses from specific patient groups in order to improve services or collect Quality and Outcomes Framework (QOF) data. In addition, all of these systems now integrate with automated check-in screens. Patients can notify the general practice of their arrival for a consultation more efficiently. A few presses on a touch screen kiosk updates the GPSoC of the patient's arrival for their consultation and the patient receives confirmation of their appointment in seconds, without administration staff having to take any action.

EMIS is the clinical system of choice used by 67% of practices across the NIHR Clinical Research Network: West Midlands (CRN WM) and the customisable options it offers, provides us with an opportunity to pilot its use in the collection of additional, brief research data from consulting patients.

2 AIM & OBJECTIVES

The aim of this study is to examine patient acceptability, for providing brief research information, whilst self-completing an automated check-in screen prior to any general practice consultation.

Primary objective

The specific objectives of this study fall into two categories; research evaluation and process evaluation. By piloting the use of the automated check-in screen to collect additional research data, the answers to these objectives will then provide feasibility information on the future use of the automated check-in screens for the identification of potentially eligible participants that would be happy to be contacted about future research studies relevant to their health and with information on patient acceptability of answering simple research questions, within the general practice waiting room.

Research evaluation objectives:

1. To examine completion rates of the two additional research questions on the automated check-in screen.
2. To estimate the number of patients that would be happy to be contacted about future research studies relevant to their health.
3. To estimate the number of patients reporting degrees of pain and which severities of pain.
4. To explore any demographic variances in completion responses.
5. To estimate research question completion rate feasibility, for future use of automated check-in screens in the collection of research data.

Process evaluation objectives;

1. To assess patient acceptability of answering an additional two research questions within the waiting room, whilst completing an automated check-in screen.
2. To explore research question completion rates depending on the time differences between; check-in completion, booked appointment time and actual consultation time.
3. To assess the impact of check-in completion for general practice operationalisation.
4. To describe the quantity and detail of any participant queries, made as a result of asking two additional research questions on the patient automated check-in screen.

3 STUDY DESIGN

This pilot feasibility study will examine patient acceptability of completing two research questions following automated check-in, within participating general practices.

Ethical approval will be sought for the collection and analysis of the additional two pieces of research data collected at the point of automated check-in by the patient, together with associated simple operational and demographic data. In line with the definition outlined in Article 4(11) of the GDPR guidance, “any freely given, specific, informed and unambiguous indication of the data subject’s wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her”[6], participants will be recruited to this study. Consent to participate will be implied by question completion. An invitation poster will be displayed next to the automated check-in screen providing general information on the study, together with participant information leaflets

providing details on how any affirmative action made can be changed and will also contain contact details for the AC DC study team, should the patient wish to ask any questions about the study.

3.1 Study population

All patients of age 18 and over, who can read and respond in English and with a booked appointment, consulting with any Health Care Professional (HCP) at their general practice, during the recruitment period will be eligible to participate. All patients are required to confirm their attendance at the general practice by using the automated check-in screen. If the patient completing the automated check-in screen is 18 years of age or over, the additional research questions will appear for completion. The additional research questions will not appear on any subsequent appointment check-in screen during the recruitment period, for those participants who have already completed the questions.

3.1.1 Eligibility

Inclusion criteria

- Patients 18 years of age or over attending participating general practices for a consultation with any healthcare professional.
- Patients registered with the participating general practice during the specified recruitment period.
- Patients able to read and respond in English.

Exclusion criteria

- Patients under the age of 18 attending the general practice for a consultation with a healthcare professional.

4 STUDY SETTING

Selected general practices within NIHR Clinical Research Network: West Midlands (CRN WM) whose GPSoC is EMIS, will host the additional two research questions on their automated check-in screen, within the patient waiting room area, for a period of 3 weeks recruitment per practice. The general practice EMIS system will require Automated Arrival facilities, to include a Questionnaire Module and an automated arrivals check-in touchscreen. This will enable any answer to a displayed question to have a Read / SNOMED code applied directly into the patient record without the need for administrative input. The study Health Informatics Specialist will coordinate the installation of the required software in participating practices (where a Questionnaire Module is not already available) and programme the check-in function to provide the additional research questions.

The average list size of CRN WM general practices is 7,500 and the minimum required appointments required per week, per 1,000 patients is 72[11]. This will provide the study team with enough data to understand patient acceptability of completing two research questions in the general practice waiting room following automated check-in, per practice.

5 STUDY PROCEDURES

5.1 Recruitment

Patients book appointments for consultations with multiple HCPs at their registered general practice by either telephoning the practice and booking an appointment, physically attending the practice and booking an appointment or by booking appointments using the practice on-line services (if available). The management and administration of this process at a general practice, is coordinated by the Practice Manager alongside the practice administration team. Once patients attend for their booked appointment, the automated check-in screen provides efficiencies for the practice administration team, as patients are empowered to self-check-in.

5.2 Patient identification

During the recruitment period for each participating practice, all patients 18 years of age or over and able to read and respond in English attending for a booked appointment and completing an automated check-in screen confirming their attendance will be eligible to participate in the study.

The study will be advertised at each participating general practice during the 3-week recruitment period. An invitation poster will be on display informing patients of the study and Participant Information Leaflets (PIL) will be available next to the automated check-in screen for patients to take away if they wish. The poster and PIL will provide general information on the study, together with contact details for the research study team should the patient wish to ask any questions about the study or clarify the research process before deciding whether or not to participate. The PIL will also contain information on how patients can withdraw any information provided for the study.

Following a patient using an automated check-in screen to confirm their attendance for a booked appointment by selecting the day of the month they were born, the month they were born and then the first letter of their surname (as standard), the additional research questions will appear for completion. Only once the research questions have either been answered, 'skipped' or sufficient time has elapsed without a response, will the check-in screen provide confirmation of the patient's attendance.

5.3 Screening

The two research questions will not appear for patients checking-in for a booked appointment who are under the age of 18 years or for those that have already answered the research questions during the recruitment period.

5.4 Research questions

Following entry of the standard identification items, to confirm attendance for a booked appointment, a patient will be presented with the first research question for completion. The first research question to appear on the check in screen will be;

"How much bodily pain have you had during the past 4 weeks?"

With options for completion of;

"None", "Very mild", "Mild", "Moderate", "Severe", "Very severe"

or

"Skip question"

Once a response to the question has been selected, the second research question will appear;

"Would you be happy for your practice to contact you about any future research studies which are relevant to your health, to improve care for patients in the NHS?"

With options for completion of;

"Yes, I'd be happy for you to contact me about research of relevance to me", "No, thank you"

or

"Skip question"

If the patient takes no further action once the first research question appears, the screen awaits a response and after sufficient time has elapsed without a response, the automated check-in screen will return to the 'Home' screen, after confirming checked-in attendance for the booked appointment. The second question will therefore not be displayed.

If the patient answers the first research question however takes no further action once the second research question appears, again the screen awaits a response and after sufficient time has elapsed without a response, the automated check-in screen will return to the 'Home' screen, after confirming checked-in attendance for the booked appointment.

5.5 Consent

Consent to participate in this study will be obtained, in line with the definition outlined in Article 4(11) of the GDPR guidance, “any freely given, specific, informed and unambiguous indication of the data subject’s wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her”[6]. Consent to participate will therefore be implied by question completion. The study invitation poster and PIL (displayed alongside the automated check-in screen for the period of recruitment) will explain the purpose of the study, what is involved and what will happen to data that the participant supplies. No patient identifiable information will be collected. Completion of the research questions will be taken as consent to participate in the study.

5.6 Data collection

A psuedonymised data extraction, for all booked appointments scheduled and attended during the three-week recruitment period at each participating practice, for those patients of age 18 years or older, will be downloaded. Data to be included in the download will include; patient demographic data (gender and age), date and times (of patient check-in, booked appointment and consultation), check-in ID (system user / practice) and self-reported answers to the two research questions. These items will form the basis of the quantitative data collection, see Table 1 for data items and from where the quantitative data will be collected.

For each participating practice, metadata to include; practice list size, demographic data (gender and age), deprivation score and total number of practice based consultations booked over the three-week recruitment period, will also be collected at aggregate level.

Participant data provided in terms of check-in queries, made as a result of the two additional research questions on the patient automated check-in screen will be anonymously logged by practice administration staff, to assess the impact of check-in completion for general practice operationalisation. The log of queries will be populated for a total of 4 weeks. Three weeks, during recruitment to the study and for one week following the end of recruitment.

Automated check-in data collection

Patients will be asked to complete two self-report research questions during automated check-in for a booked appointment at their general practice. The data entered will be appended to their electronic medical record and psuedonymised data will be downloaded, for all patients for whom the research questions appeared. This data will consist of unique study identifiers, gender, age, times (check-in, booked and consultation), check-in ID (system user / practice) and the study research coded entries.

Table 1: Data items and method of data collection

Data items	Description	Method of data collection
Patient demographics	Gender	EMIS data extraction
	Age	
Date and time of:	Check-in	
	Booked appointment	
	Consultation	
Check-in ID	Dichotomous: 'System user' or 'Practice'	
Degree of bodily pain experienced during the past 4 weeks.	Single question: 1-6 point scale – degree of pain	Patient self-reported
Consent to contact about future research studies of relevance.	Dichotomous: Yes or No	

5.7 Long term use of data collected

Data collected on the degree of bodily pain experienced during the past 4 weeks will be retained at the general practice. The response provided as to whether the patient would be happy for their practice to contact them about any future research studies relevant to their health, will be a clinical coded entry retained in the patient's electronic medical record, unless the patient requests to amend their response or if processing operations or purposes evolve[14].

5.8 Withdrawal criteria

Patients will be able to withdraw data provided for the study by either contacting a member of the AC DC study team or by informing practice administration staff of the amendment they would like to make to entered data. This therefore provides patients with up to a 4 week 'cooling off' period (before psuedonymised data is downloaded) should they wish to retract or amend their participation in the study.

Patients will be able to amend their response at any time in the future, to whether they are happy for their practice to contact them about any future research studies which are relevant to their health. To amend their response to this question they will need to inform the practice administration staff.

5.9 End of study

At each participating practice, recruitment will be ongoing for 21 consecutive days and a psuedonymised data extraction will be made for the 21-day recruitment period on or after day 28. The psuedonymised data extraction and meta data will be extracted by practice administration staff and securely transferred via nhs.net email to the Research Institute for Primary Care and Health Sciences (iPCHS). The study will last for 21 days at each participating general practice, after which time the additional two research questions will be removed from the automated check-in screen and the invitation poster and PILs removed from the general practice waiting room. The AC DC participant query log populated by general

practice administrative staff will be maintained for a period of 4 weeks at each participating general practice.

The end of the study is defined as the collection of data from the last participating practice. The HRA will be notified of the end of the study in accordance with Keele University SOPs.

6 STATISTICS AND DATA ANALYSIS

6.1 Sample size calculation

The average list size of CRN WM general practices is 7,500 patients, of which approximately 6,000 (80%) will be 18 years of age or over. With the minimum required appointments, per week, per 1,000 patients being 72[11]. Assuming the same rate of appointment use in those under and over 18 years, there will be an average of 432 appointments per week for those aged 18 years of age or over. Over three weeks therefore, discounting an approximate 10% of patients who have either; >1 appointment booked within the three-week period, lack capacity to complete the automated check-in screen, or the appointment is for either a telephone appointment or a home visit, the practices can expect approximately 1166 eligible participants.

One of the outcomes of this study is to estimate the proportion of people who are happy for their practice to contact them about any future research studies which are relevant to their health. Assuming that approximately 50% will respond positively to this question, 9604 people will need to respond to the question in order to estimate a 95% confidence interval for this proportion formally with a precision of 0.01. Assuming that 80% of those who use the automated check-in complete the additional questions, this would require approximately 12005 people to complete an on-screen check-in in order to achieve sufficient responders. This equates to approximately 11 practices displaying the questions for 3 weeks each, dependent on practice size and actual use of the automated check-in screens.

One AC DC participant check-in query log per practice, completed by practice administration staff, with regards to queries made as a result of the two additional research questions on the patient automated check-in screen, will allow the study team to assess the impact of check-in completion for general practice operationalisation.

6.2 Statistical analysis plan

Simple descriptive statistics will be used to compare any demographic differences between responders and non-responders and to characterise the study sample. This is a descriptive study and we will determine frequencies and percentages of responses to the 2 questions, stratified by age, gender and practice. Mean or median times (as appropriate) between check-in, booked appointment and time of

consultation will be calculated in responders and non-responders separately. In the production of and reporting on subgroups, ONS guidance will be followed on statistical microdata, to ensure the confidentiality of individual persons is protected[13].

Thematic content analysis will be used to interpret the participant data logged by practice administrative staff.

In accordance with Keele University SOPs, a Statistical Analysis Plan (SAP) will be completed prior to the end of recruitment.

7 DATA HANDLING

Data management will be carried out in accordance with a Study Data Management Plan, in accordance with Keele University Standard Operating Procedures (SOPs). The study data extracted will contain only psuedonymised data, which will be stored on Keele University servers and password protected. All confidentiality arrangements adhere to relevant data protection regulations and guidelines (General Data Protection Regulation (GDPR), Caldicott, General Medical Council (GMC), Medical Research Council (MRC) UK Policy) and the Chief Investigator and Study Statistician (Data Custodian) have responsibility to ensure the integrity of the data and that all confidentiality procedures are followed. At the end of the study, data will be securely archived in line with the Sponsor's procedures for a minimum of 10 years after publication of the main findings and until the sponsor authorises destruction. Archiving will be carried out in accordance with Keele University SOPs.

Any subsequent requests for access to the data from anyone outside of the research team (e.g. collaboration, joint publication, data sharing requests from publishers) will follow the Keele University SOP data sharing procedure.

8 MONITORING & AUDIT

8.1 Study Management

The study Chief Investigator (CI) is responsible for the conduct of the study and will convene a Study Management Group (SMG) comprising members of the research team. Study management will be carried out in accordance with Keele University SOPs. The SMG will meet at regular intervals throughout the study and will be responsible for the set-up, ongoing management and monitoring and for the interpretation of the results. The SMG will oversee: the protocol completion; obtaining regulatory approval and site set-up; reporting of unexpected events to the REC and Sponsor; monitoring of

screening and recruitment procedures; data collection and software development; completing regulatory reporting requirements.

The CRN WM, will co-ordinate the general practice identification process and co-ordinate local implementation and study set-up for the study team.

8.2 Monitoring arrangements

Study monitoring will be carried out in accordance with a Study Monitoring Plan and Keele University SOPs which lay out the procedures for monitoring the data collection, protocol compliance and data management procedures.

On day 3 of recruitment, an export will be downloaded by general practice administration staff and securely sent to iPCHS via nhs.net email, as a monitoring arrangement to confirm data collection functionality.

8.3 Safety Reporting

No serious or unexpected adverse events are expected as a result of this study.

Data entered with regards to bodily pain experienced over the last 4 weeks will be filed chronologically in the patients' medical record, accessible to the HCP the patient is booked to consult with. The time frame between a patient reporting any bodily pain and being seen by a HCP will be minimal and HCPs will be aware of the study and that the pain score is being collected.

8.4 Study timeline

May 2018 – June 2018:	Finalise study documentation and study technological requirements.
July 2018:	NIHR Clinical Research Network Portfolio adoption.
	Liaison with general practices.
	Obtain ethics and regulatory governance approvals.
November 2018 – April 2019:	Recruitment
May 2019 – July 2019:	Data cleaning and data analysis.
From July 2019:	Dissemination

9 ETHICAL AND REGULATORY CONSIDERATIONS

Health Research Authority (HRA) approvals will be applied for and sought before the study commences. HRA Approval is the process for the NHS in England that brings together the assessment of governance and legal compliance, with independent Research Ethics Committee opinion provided through the UK Health Departments' Research Ethics Service.

9.1 Research Ethics Committee (REC) review and reports

The study will be submitted to and approved by a Research Ethics Committee (REC) under proportionate review and the appropriate Site Specific Assessor for each participating site prior to entering participants into the study.

Following initial approval from the REC, the REC will be updated of the study progress in line with Keele University SOPs.

9.2 Patient and Public Involvement and Engagement

In the UK there is a clear policy directive to involve patients and the public in research[12]. Such involvement will lead to research that is of greater relevance and of better quality. Keele University have an established Research User Group (RUG) who provide advice and feedback on study/trial conduct and offer patient and public representation on studies.

Patient involvement pre-study (April 2018)

8 patients from Keele's RUG have helped to develop the study in the following ways:

RESEARCH DESIGN:

Question development

Patients have assessed the proposed research questions (and discussed the required patient facing documentation) in terms of content, layout, style, order of questions, and overall length.

Data collection processes

Patients have helped to ensure presentation, content and functionally are acceptable for use within a general practice waiting room.

DISSEMINATION:

Results from the pilot feasibility study will be presented back to the RUG as they are interested in the acceptability of the intervention and would like to be involved in any amendments that are required should the study methodology be rolled out further for future research.

9.3 Regulatory compliance

Before any site can enrol patients into the study, the CI or designee will apply for HRA approval. For any amendment see section 9.7.

9.4 Protocol compliance

All instances of protocol deviations will be assessed for severity by the CI (or their delegate), in accordance with the study protocol and using the Sponsor's GCP and Protocol Deviations FOR25.1 Initial Report.

Both Corrective and Preventative actions should be considered to both correct the deviation and/or prevent the deviation from occurring again.

9.5 Data protection and patient confidentiality

All information collected during the course of the study will be kept strictly confidential. Information will be held securely and managed electronically by Keele University and in accordance with Keele University SOPs.

9.6 Indemnity

This study is sponsored by Keele University and Keele University will be liable for negligent harm caused by the design of the study.

The NHS has a duty of care to patients treated, whether or not the patient is taking part in a clinical research study, and the NHS organisation remains liable for clinical negligence and other negligent harm to patients under this duty of care.

9.7 Amendments

The need for any potential protocol amendment will be raised with the CI and will be discussed with both the SMG and Sponsor prior to being agreed. Updated versions of the protocol will not be circulated for use until the appropriate regulatory parties have approved the amendment, at which point every effort will be made to implement this updated protocol as soon as is practicably possible, superseding the previous version and documenting the date at which the new protocol was implemented.

10 DISSEMINATION

10.1 Dissemination policy

The Research Institute for Primary Care and Health Sciences (iPCHS) has a dedicated infrastructure, linked to strong regional, national and international health care and academic networks, which facilitate dissemination of our research findings to key policy, commissioning clinical, health education and patient stakeholders. The research team will be able to access our dedicated infrastructure to identify and promote research outputs that lend themselves to translation by health providers. Our strong regional partnership with the NHS (formalised through the Primary Care Research Consortium) and our leadership of the Person Centred Care programme of the West Midlands' Academic Health Sciences Network provides further mechanisms to secure effective dissemination of our research findings at national and European levels, through access to the European Innovation and Technology funding streams. The study findings will be published in a peer-reviewed journal and made available via open access.

10.2 Dissemination plan

Dissemination will focus upon results addressing each of the study objectives. Results will be presented at relevant national conferences (e.g. Society of Academic Primary Care) and international conferences (e.g. World Organisation for Family Doctors). Findings will be disseminated to HCPs from participating general practices via a newsletter. Dissemination will also take place through the iPCHS Twitter account and blog. The study team will also work with the Keele RUG to provide lay summaries which will be sent to the patient panels at each of the participating primary care general practices.

11 REFERENCES

1. NHS England, 2016. General Practice Forward View.
2. Williamson, C. (2016). Electronic self check-in for patients: the costs and consequences. The British Journal of General Practice, 66(644), 145.
3. Chambers, R. (2017). Code of practice for technology enabled care services for Staffordshire Local Digital Roadmap. Staffordshire Digital Design Authority (SDDA).
4. Chambers R, Schmid M. Making technology-enabled health care work in general practice. British Journal of General Practice 2018, Vol. 68, Issue 668, March 2018
5. Health Education England, Royal College of Nursing. (2017) Improving digital literacy (RCN, London).
6. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free

movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). Official Journal of the European Union, L 119/1.

7. Irving G, Neves AL, Dambha-Miller H, et al International variations in primary care physician consultation time: a systematic review of 67 countries BMJ Open 2017;7:e017902. doi: 10.1136/bmjopen-2017-017902
8. Phillips C, Main CJ, Buck R, Aylward M, Wynne-Jones G, Farr A. Prioritising pain in policy making: the need for a whole systems perspective. Health Policy. 2008;88:166–175.
9. NHD Digital, Freedom of information request NIC-105967-B8X4C, May 2017.
10. www.emishealth.com
11. British Medical Association. Safe working in general practice. 2016.
12. NHS Executive. Health Service Circular 1999/210 Patient and public involvement in the new NHS. Leeds; NHS Executive Quality and Consumers Branch. 1999.
13. Office for Statistics Regulation. Code of Practice for Statistics. Edition 2.0, February 2018.
14. Information Commissioner's Office. Consultation: GDPR consent guidance. 2017.