FULL/LONG TITLE OF THE STUDY

A realist-informed investigation of the organisation and delivery of health and social care services for people with fibromyalgia living in the UK.

SHORT STUDY TITLE / ACRONYM

Understanding health services delivery for fibromyalgia

PROTOCOL VERSION NUMBER AND DATE

V2 [15.11.2020]

RESEARCH REFERENCE NUMBERS

IRAS Number:	275725
SPONSORS Number:	2-068-20
FUNDERS Number:	21958

SIGNATURE PAGE

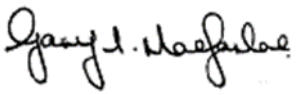
The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

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 investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly 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: 15/11/2020



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Name: (please print):

PROFESSOR GARY MACFARLANE

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KEY STUDY CONTACTS

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Joint-sponsor(s)/co-sponsor(s)	N/A
Funder(s)	Versus Arthritis Copeman House, St Mary's Court St Mary's Gate Chesterfield S41 7TD
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Committees	N/A

STUDY SUMMARY

Study Title	A realist-informed investigation of the organisation and delivery of health and social care services for people with fibromyalgia living in the UK.
Internal ref. no. (or short title)	Understanding health services delivery for fibromyalgia.
Study Design	Qualitative case study design
Study Participants	Up to ten UK-based case studies will be conducted in total: at least one in England, Scotland and Wales. Participants will include healthcare professionals (for example, doctors, nurses, allied health professionals), social care practitioners (for example, social prescribers), service delivery managers, commissioners and other individuals involved in the organisation and delivery of health and social care services for people with fibromyalgia living in the UK.
Planned Size of Sample (if applicable)	Interviews - approximately 10 participants per case study (total 100 participants). Qualitative observations (in-person or on-line) involving similar numbers of people (total 100 participants). Online focus groups with approximately 6 to 8 participants per group (up to ten groups - total 60-80 participants)
Follow up duration (if applicable)	N/A
Planned Study Period	January 2021 – January 2022
Research Question/Aim(s)	This research study aims to: i) Explore and understand how health and social care for people with fibromyalgia living in the UK is organised and delivered. ii) Identify models of practice to inform codesign of new care pathways for people with fibromyalgia living in the UK.

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	FINANCIAL AND NON FINANCIAL SUPPORT GIVEN
Versus Arthritis (funding)	£1,185,670.91 (PAtient-centred Care for Fibromyalgia: New pathway Design [PACFiND] research programme funding – 60 months)

ROLE OF STUDY SPONSOR AND FUNDER

i) The University of Aberdeen, as the study sponsor will be responsible for initiation, management and reporting of the study and will ensure appropriate indemnity before the study starts.

ii) Versus Arthritis as the funder, will provide staff, travel and subsistence, and transcription costs associated with the conduct of this study.

iii) The design, management, analysis and reporting of the study will be entirely independent of the funder.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

A study management team, including the Chief Investigator, deputy Chief Investigator, study manager, academic and clinical staff, will be responsible for the delivery of this study. The study management team will provide guidance and expert advice to the researchers on all aspects of this study through monthly teleconference meetings and email/telephone correspondence as necessary. The study management team will, in turn, be supported by a wider all-investigator team associated with the PACFiND programme, who will provide advice and guidance about issues arising.

Patient & Public Involvement Group

In addition to our two patient research partners (DD and SS) who are members of the study management team, a local patient and public reference group of 8 to 10 members has been convened in South London to advise on the development and co-ordination of this research. The group will

ensure that the research undertaken is accountable, transparent and relevant to patients and the public. Members of the group will provide a patient and public perspective on the research, read and review research project documents, highlight any issues of concern relating to ethics and governance of the study, and advise on and be involved in the dissemination of the study findings. Two further patient and public reference groups (one each in Scotland and Wales) will also be established to advise on and support the study.

PROTOCOL CONTRIBUTORS

Principal Investigators:

Dr Nicky Wilson, King's College Hospital NHS Foundation Trust & Professor Catherine Pope, Nuffield Department of Primary Care Health Sciences, University of Oxford.

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KEY WORDS:

Fibromyalgia
Case study
Realist research
Health service delivery

STUDY FLOW CHART

Case study research gantt chart

	2019	2020						2021					
	Nov-Dec	Jan-Feb	Mar-Apr	May-Jun	Jul-Aug	Sept-Oct	Nov-Dec	Jan-Feb	Mar-Apr	May - Jun	Jul-Aug	Sept-Ocr	Nov-Dec
Understanding heath services delivery for fibromyalgia													
Case studies x 10													
Protocol development													
Patient & Public Involvement													
Selection of case study sites													
Ethics application													
Site specific R&D permissions													
B2 familiarise / build contacts													
Data collection													
Data analysis													
Write up													

STUDY PROTOCOL

A realist-informed investigation of the organisation and delivery of health and social care services for people with fibromyalgia living in the UK.

1 BACKGROUND

Fibromyalgia is a multi-symptom long-term condition that affects approximately 2% of the general population (Heidari et al. 2017). It is characterised by persistent generalised pain, fatigue, cognitive symptoms, unrefreshing sleep and psychological distress (Wolfe et al. 2016). While recovery from fibromyalgia is possible (Grape et al. 2015), many individuals report ongoing pain and disability decades after diagnosis, and the personal, social and economic impact of fibromyalgia is substantial (Sim & Madden 2008; Mengshoel & Grape 2017; Arnold et al. 2019).

Furthermore, diagnosis of fibromyalgia can be challenging. Patients report that the lead up to diagnosis is often protracted and punctuated by consultations with different healthcare providers during which hopes are raised and dashed (Mengshoel et al. 2018). For clinicians, the lack of conclusive diagnostic laboratory and imaging tests, and the variable nature of the condition is problematic, often resulting in healthcare provider and patient frustration and dissatisfaction (Briones-Vozmediano et al. 2013; Arnold et al. 2019).

Dissatisfaction with healthcare services often persists after diagnosis (Mengshoel & Grape 2017) despite the existence of evidence-based non-pharmacological and pharmacological interventions to treat and manage the signs and symptoms of fibromyalgia (Macfarlane et al. 2017). Patient experiences of UK based healthcare services reflect unmet need (Lempp et al. 2008; Patient and Client Council 2016) and there is a lack of a universally accepted model or package of health and/or social care for all patients with the condition (Able et al. 2016; Doebl et al. 2020). This negatively impacts quality improvement activities, patient empowerment, and ultimately, outcomes for people with fibromyalgia.

To address this issue, the University of Aberdeen, in collaboration with a number of other universities in the UK and the University of Michigan, has received funding from the charity Versus Arthritis to develop new pathways of care with and for people with fibromyalgia. PAtient-centred Care for Fibromyalgia: New pathway Design (PACFiND) is a five-year funded programme of work that seeks to develop better services for people with fibromyalgia (https://www.abdn.ac.uk/iahs/research/epidemiology/pacfind-1483.php). This study is one component of the PACFiND research programme and seeks to understand how health and social care is currently

organised and delivered to people with fibromyalgia living in the UK to help identify what works, for whom and in what circumstances.

2 RATIONALE

Health and social care interventions (e.g. drug therapy) or packages of inter-related interventions (e.g. drug therapy plus counselling) work differently for different groups of people under different conditions in different settings (Pawson & Tilley 1997). Developing and refining a transferable theory (or theories) about *how* interventions or packages of inter-related interventions (from here on referred to as 'programmes') deliver particular outcomes for people with fibromyalgia, will potentially open up opportunities to improve health-related outcomes and patient satisfaction for people with fibromyalgia living in the UK.

Building a programme theory (or theories) to underpin the organisation and delivery of health and social care for patients with fibromyalgia, from which new pathways or models can be advanced, is likely to be of benefit to people with fibromyalgia, their families and carers, health and social care practitioners and policy makers concerned with the organisation of health and or social care.

3 THEORETICAL FRAMEWORK

Realist-informed qualitative case studies will be undertaken to explore and understand how health and social care programmes delivered to people with fibromyalgia living in the UK work and bring about their effects (Pawson & Tilley 1997; Exworthy et al. 2012; Russell et al. 2015). Realist research approaches aim to tease out for a particular programme what works, for whom, and in what circumstances, in order to develop and/or refine a transferable theory or set of theories that can be used to guide future programme design, planning and implementation in different settings (Wong et al. 2016).

Realist investigations focus on the causal mechanisms by which programmes bring about specified outcomes in different settings. In realist terminology, context (C), mechanism (M) and outcomes (O) form configurations (context-mechanism-outcome configurations (CMOCs)) that are central to enquiry (Pawson & Tilley 1997).

The detection of CMOCs commonly starts with the identification of specified outcomes, with explanations about the causal mechanisms of these outcomes informed by an initial rough programme theory (Shearn et al. 2017). In this study, key outcomes of interest will focus on what matters to people with fibromyalgia and will be developed through patient and public involvement workshops, informed

by patient experience literature and interviews conducted with people with fibromyalgia gathered from other research studies associated with the PACFiND programme.

4 RESEARCH AIM(S)

1. Explore and understand how health and social care for people with fibromyalgia living in the UK is organised and delivered.

2. Identify models of practice to inform codesign of new care pathways for people with fibromyalgia living in the UK.

4.1 Objectives

1. To develop an initial rough programme theory (or theories) to guide and structure data gathering, analysis and synthesis within and across the case studies.

2. To describe existing care practices and processes associated with identifying and supporting people with fibromyalgia in relation to outcomes that matter to people with fibromyalgia living in the UK.

3. To identify, map and explain the causal mechanisms associated with change / outcomes that matter to people with fibromyalgia living in the UK.

4. To specify *key* CMOCs within and across case studies.

5. To develop a realist programme theory (or theories) underpinning positive outcomes in relation to identifying and supporting people with fibromyalgia living in the UK.

4.2 Outcome

A primary focus of data collection during the case studies will be on outcomes that matter to people with fibromyalgia. A preliminary set of outcomes has been developed, informed by peer-reviewed literature about patient experiences of living with and managing fibromyalgia (for example, Mengshoel and Grape 2017; Mengshoel et al. 2018; Muraleethran et al. 2018) and data taken from new interviews conducted with people with fibromyalgia as part of the wider PACFiND programme. These are:

i) Validation of patient experiences of signs and symptoms of fibromyalgia and prompt diagnosis.

ii) Interactions between people with fibromyalgia and health and/or social care providers that generate hope, are individualised and patient-centred, and focussed on 'what matters to me' through processes of shared decision making.

iii) Recognition of fibromyalgia as a disability (Barber et al. 2019).

iv) Sustained and supportive relationships with skilled and knowledgeable health and/or social care providers over time to help build self-management and facilitate re-integration into life and society.

v) Prompt access to interventions/programmes of health and/or social care that are coordinated across providers.

vi) Increased knowledge, skills and confidence to manage independently.

These outcomes will be further developed and refined through discussions with members of our affiliated patient and public reference groups.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYSIS

We will purposively sample up to ten qualitative case studies in the UK to explore current health and social care pathways for identifying and supporting people with fibromyalgia living in the UK. Case studies may include one service/provider or multiple services/providers (NHS or non-NHS) within a locality, reflecting configurations and delivery of health and social care services for people with fibromyalgia.

Data collection

We will:

a) Gather documentary evidence, such as: policy and strategy documents; local care pathways and services processes relating to the provision of health and social care for people with fibromyalgia or signs and symptoms suggestive of fibromyalgia; staff training and development documents and service and programme evaluations.

b) Undertake focussed observations (in-person or on-line depending on the coronavirus pandemic situation) of the work done by staff relating to i) the practices and processes associated with identifying people with fibromyalgia and ii) the organisation and delivery of care to support people with fibromyalgia. Observations, (which may include informal conversation with staff during quiet periods) will focus on outcomes that matter to people with fibromyalgia and the circumstances within which these outcomes emerge or not. As part of our ethnographic work, we will capture information about: (i) providers, such as the type, skill mix and capacities of health and social care worker(s) associated with the delivery of a programme; (ii) programmes of care, including the location, duration and nature of interventions (for example face-to face or remote interventions); (iii) the circumstances in which programmes are delivered (for example, organisational culture and constraints); and (iv) inter-personal interactions (for example, between staff and patients, staff and others) in order to understand the infrastructure underpinning a programme (Pawson 2006). Data will be collected via field notes using an observation record template and later word processed.

c) Undertake face to face, telephone or on-line semi-structured interviews with staff delivering /organising health and social care for people with fibromyalgia. The aim of the interviews will be to explore participant's views and experiences of circumstances influencing outcomes that matter to people with fibromyalgia in relation to identification and support of people with the condition, in order to build explanations about what works, how it works and the circumstances in which it works. A topic guide (see Interview schedule) will inform the interviews. Face-to-face or telephone interviews will be digitally audio-recorded, encrypted and subsequently transcribed verbatim. On-line interviews will be audio-recorded using Microsoft Teams. Data will be de-identified at the point of transcription. In line with the development of a realist programme theory (or theories), up to two shorter follow up interviews may be requested with participants to clarify any supplementary related points (Manzano 2016). These can be conducted by telephone, email or on-line.

d) Undertake on-line focus groups within and or across case studies with key stakeholders involved in the organisation and delivery of healthcare services for people with fibromyalgia. The aim of the focus groups will be to further develop a realist programme theory (or theories), through integration of stakeholder theory with middle range theories, about how programmes of care for people with fibromyalgia work. Focus groups enable participants to build on each other's views, and explanations or theories underpinning positive outcomes relating to identification and support of people with fibromyalgia will be presented to participants for confirmation and refinement (Astbury 2018). A deliberative discussion focus group approach will be taken (Rothwell et al. 2016), using both live chat and discussion boards over a period of one week to allow reflection and development of the discussion. The online groups and discussion boards will be facilitated and moderated by members of the research team. A topic guide will be further developed (see outline focus group sample guide), drawing on data gathered during observations and interviews to formulate theory or theories, to guide the focus groups discussion. Live online discussion sessions will take place on Microsoft Teams and will be audio-recorded directly from Microsoft Teams. The recording will be encrypted and subsequently transcribed. Microsoft Teams channels with access restricted to specified users will be used for discussion boards. The discussions in the Microsoft Teams chat feature will be copied and pasted into word documents. All data will be de-identified at the point of transcription/extraction.

Data will be collated using Microsoft Word and Excel packages available to the researchers.

Data analysis

Data management and analysis will be aided by qualitative data software (NVivo) and informed by a realist approach. Following familiarisation with the data, initial coding of texts from observations and interviews will focus on descriptions of the actual practices and processes underpinning an intervention/programme, observed outcomes, the contextual conditions and the mechanisms, in order to formulate of a range of CMOCs for each case. Analysis of data will be iterative. Subsequent development of codes will focus on theory-driven interpretations of the data informed by an initial rough programme theory (or theories). Within each case, CMOCs will be compiled into narrative summaries and represented in tabular and or diagrammatic form to facilitate comparison within and between case study sites. This will enable the development and refining of the initial rough programme theory (or theories) into one or more realist programme theories underpinning the organisation and delivery of health and social care for people with fibromyalgia. Focus group discussions will be analysed thematically (Braun and Clarke, 2006).

Whilst a realist methodology will guide data analysis, we recognise that the distinction between mechanisms and contexts may not be clear-cut (Shaw et al. 2018). Therefore, we will also adopt a wider comparative case study analytic lens (Dopson and Fitzgerald, 2009) and take an interpretive holistic approach to understanding our cases and how they compare with others.

The final set of CMOCs and realist programme theory or theories resulting from the case studies will be used as a framework for a subsequent co-design study within the PACFiND research programme.

6 STUDY SETTING

Up to ten case studies will be selected. There will be a minimum of one case study in England, Scotland and Wales. Case studies may include one service/provider or multiple services/providers within a locality, reflecting configurations and delivery of health and social care services for people with fibromyalgia.

Health and social care delivered to people with fibromyalgia will be the unit of interest of our case studies.

Our choice of case studies will be informed by the intersection of four dimensions - (i) providers and personnel (for example NHS primary/secondary care and or non-NHS services); (ii) the nature of programme(s) delivered to people with fibromyalgia; (iii) inter-relations/local pathways connecting providers, services and organisations and (iv) local accessibility arrangements and permissions.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

7.1.1 Inclusion criteria

<u>Case studies</u>

1. NHS and/or non-NHS organisations in the UK providing health and social care to people with fibromyalgia.

<u>Interviews, observations and focus groups</u>

1. Health and social care professionals identifying and or providing support for people with fibromyalgia in one of the ten case studies.
2. NHS/non-NHS staff influential in the organisation and/or delivery of health and social care to people with fibromyalgia in one of the ten case studies, for example, service managers, professional service leads, commissioners.

7.1.2 Exclusion criteria

Case studies

1. NHS/non-NHS organisations in the UK not providing health or social care to people with fibromyalgia.

Interviews, observations and focus groups

1. NHS/non-NHS staff who are not able to communicate sufficiently well in English to participate effectively.

7.2 Sampling

7.2.1 Size of sample

Two professors (Pope and Locock) with combined experience of conducting case study research in healthcare totalling nearly 60 years designed this study. The numbers of cases are in line with sample sizes and case selection for numerous funded and successfully completed NIHR and charity funded projects using case study approaches. Please see for example:

Pope C, Halford S, Turnbull J, Prichard J, Calestani M, May C. Using computer decision support systems in NHS emergency and urgent care: ethnographic study using normalisation process theory. BMC Health Serv Res. 2013 Mar 23;13:111. doi: 10.1186/1472-6963-13-111. ;

Turnbull J, Pope C, Rowsell A, et al. The work, workforce, technology and organisational implications of the '111' single point of access telephone number for urgent (non-emergency) care: a mixed-methods case study. Southampton (UK): NIHR Journals Library; 2014 Feb. (Health Services and Delivery Research, No. 2.3

Locock, L. Montgomery, C., Parkin, S. et al. How do frontline staff use patient experience data for service improvement? Findings from an ethnographic case study evaluation.
J Health Serv Res Policy, 2020, 25:151-161.

Case study sites

We will select up to ten case studies in the UK (at least one will be from England, Scotland and Wales) in order to capture a variety of contemporary NHS and non-NHS health and social care services delivered to people with fibromyalgia.

Observations

The exact number of observations undertaken in each case study cannot be determined in advance and will be shaped by the post-COVID health service landscape. However, we anticipate an observational period (in person or online) of up to two weeks for each case study to ensure in-depth data collection.

Interviews

The nature of ethnographic case study work informed by realist principles and the post-COVID health service landscape means that the participant sample has to remain flexible. The exact number of interviews undertaken in each case study will be dependent on the mix and configuration of staff involved in the organisation and delivery of health and social care for people with fibromyalgia and their availability. We estimate that the number of participants interviewed in each case study will be approximately ten (100 participants in total).

Online focus groups

Up to ten online focus groups with between six and eight participants per group will be conducted within and across case studies (60-80 participants in total).

7.2.2 Sampling technique

Case studies

To facilitate variation in our case studies we will construct a sampling frame incorporating a range of factors, including geographical region, primary/secondary/third sector care, co-location and or inter-related services providing health and social care for people with fibromyalgia living in the UK. We will review the findings of two national surveys recently undertaken as part of the PACFiND programme and use these in combination with intelligence about services, gathered through online searches, local contacts and insights from members of the research study team.

Interviews, observations and focus groups

Purposive sample, including staff delivering health and social care to people with fibromyalgia, service managers and professional leads involved in the organisation of health and social care for people with fibromyalgia, commissioners and policy makers.

7.3 Recruitment

7.3.1 Sample identification

Once an organisation/provider has agreed to participate in the study, a local collaborator will facilitate access to the site and potential participants. The researchers will work with local collaborators to identify relevant stakeholders to invite to participate in the study following the granting of local permissions.

7.3.2 Consent

Health and social care staff wishing to participate in the study will be required to provide written informed consent prior to taking part. Consent will be taken by the researchers responsible for conducting the study (Nicky Wilson, Catherine Pope and a Research Associate appointed to work on the study). Separate consent forms will be used for observations, interviews and focus groups. When data collection of an observation, interview or focus group is fully online, one of the researchers will read through the consent form individually with each participant and ask the participant to verbally agree to each point. This will be recorded on the consent form. In addition, verbal consent to observe interactions between participating staff and others (for example other staff during healthcare provider group meetings) will be obtained from all those involved and recorded in the observation field notes. Patients attending services during periods of observation, and non-participating staff, will be informed about the study via an information leaflet given out by one of the researchers and/or a member of the patient's direct care team. Information leaflets will also be displayed within the department. For online observations, any person who may be part of the observation will be sent an information leaflet prior to an observation taking place.
Verbal permission to observe a consultation/ interaction and make field notes will be sought from each person present during an observation. Consent will be recorded in field notes. It will be made clear to all patients attending services during periods of observations that the purpose of the research is to understand how services for people with fibromyalgia are organised and delivered and that all data gathered will relate to this and not to individual patients.

7.3.3 Withdrawal from the study

Participants can choose to withdraw from the study at any time. Withdrawals will be recorded, and permission will be sought from the participant to retain their study data up to the point of withdrawal. If a participant withdraws from the study early in the data collection phase, another participant may be approached and invited to take part in the study.

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk

Risk of harm to participants

Minimal risk of harm to participants is anticipated from involvement in this study. Participants may perceive intrusion or inconvenience as a result of having a researcher observe their clinical practice or service-related work. The researcher will endeavour to not create additional work for participants. In addition, the researcher will ensure that interviews are conducted at a convenient time for participants.

Risk of harm to patients with fibromyalgia attending NHS or non-NHS services

Patients attending services during periods of observational data collection may become distressed during consultations with healthcare providers. Should this occur, the researcher will offer to leave the room/area/virtual platform.

Risks to researchers

This study poses minimal risk of physical or emotional harm to the researchers. A risk assessment, sensitive to the local research environment, will be undertaken prior to data collection at each case study site. The researchers will follow relevant policies relating to the coronavirus pandemic, lone working and safeguarding and will seek advice if necessary.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

A favourable opinion will be sought from an NHS Research Ethics Committee and local research and development offices for participating organisations prior to commencement of the study. The study will be conducted in accordance with Good Research Practice and Good Clinical Practice guidance. Any amendments requiring ethical review will not be implemented until a favourable opinion is granted and mechanisms to implement change at a specific site are in place.

8.3 Peer review

The PACFiND programme (incorporating this study) was subject to external peer review as part of a competitive funding application.

8.4 Patient & Public Involvement

Nine patient partners, identified through the charity Fibromyalgia Action UK contributed to the development of the proposal for the PACFiND research project and two patient research partners are members of the study management team that meets monthly to discuss aspects of project design, project development and implementation. In addition, PPI groups in Scotland have contributed to the development and implementation of two studies embedded within an earlier workpackage of the PACFiND programme, the findings of which have informed this study.

In relation to the research described in this proposal, a patient and public representative group in South London of 8 to 10 people with fibromyalgia has been convened from support groups and NHS services provided by King's College Hospital NHS Foundation Trust. The group met face-to-face in January 2020 and on-line in April 2020 and will meet again on another two occasions over the duration of the study. Group members will be asked to: (i) contribute to the development of outcomes that are important to people with fibromyalgia, in relation to the organisation and delivery of health and social care services; (ii) reflect on and discuss early findings of the study and (iii) contribute to the development of narratives about the most relevant CMOCs. In addition, group members will be asked to review patient information or dissemination material. This will be done via mail or email, with information sent out at least one week ahead of meetings. Two further PPI groups (one each in Scotland and Wales) will also be established to advise on and support the study.

PPI group members will be reimbursed for attendance at meetings and for time revising study materials. Rates will be informed by INVOLVE guidance and will be context specific.

8.5 Data protection and patient confidentiality

The sponsor will act as the research data controller for this study. All members of the research study team will comply with the requirements of GDPR and the Data Protection Act 2018. Audio-recorded interview and focus group data will be encrypted and sent securely to a University of Aberdeen approved third party transcribing service provider. Notes taken during observations will be typed up on hospital or university password-protected computers. Any identifiable information will be removed from

the data at the point when it is typed up. Audio-recordings, field notes and texts from the discussion boards and chat during online focus groups, will subsequently be destroyed. De-identified data and non-paper consent forms will be uploaded by members of the research team to a password-protected drive on the University of Aberdeen's secure servers. Paper consent forms will be stored in locked filing cabinets in secure offices at the researchers place of work (Wilson, King's College Hospital; Pope & Research Associate, Nuffield Department of Primary Care Health Sciences). These data will be stored under a unique participant identification for ten years and will be accessible to the three members of the research study team only.

Participant personal data (e.g. names and contact details) will be kept electronically and stored separately within a restricted folder on a password-protected drive on the University of Aberdeen's secure servers. Only the researchers collecting data will have access to this restricted folder. Anonymised data may be shared by ZendTo with members of the research team who do not have access to this folder. Participant personal data will be deleted three months after the end of the study.

Data collected during this study will be kept confidential. However, participants, patients and non-participant staff will be informed (via Participant Information Sheets, Consent forms and the information leaflet) of the limits of confidentiality if potential safeguarding issues, poor standards of care, or malpractice are identified during the period of data collection.

Reports or publications related to the study findings will not contain information that could identify individuals or organisations.

8.6 Inspection of records

Direct access to all study records and source documentation will be granted by the Chief Investigator, Principal Investigators, and all institutions involved in the study, to authorised representatives from the Sponsor or host institution for study-related monitoring and/or audit of the study to ensure compliance with regulations.

8.7 Indemnity

The University of Aberdeen is the Sponsor of the study and holds a policy of public liability insurance for legal liabilities arising from the conduct of the study.

The researchers conducting the study will hold honorary contracts with the University of Aberdeen and will have cover under the University of Aberdeen's insurance policy.

The Sponsor does not provide study participants with indemnity in relation to participation in the study.

8.8 Access to the final study dataset

Only the researchers responsible for conducting the study and gathering data (Wilson, Pope and a Research Associate appointed to work on the study) will have access to the full data set including participant names and ID numbers. The Chief Investigator, Deputy Chief Investigator and other members of the study management team will have access to the full but de-identified data set. De-identified transcripts or extracts of transcripts may be shared with other members of the research team for analysis and discussion using ZendTo.

9 STUDY CONDUCT RESPONSIBILITIES

9.1 Protocol amendments, deviation and breaches

If a protocol or study document amendment is necessary, the Chief Investigator will seek approval from the Sponsor, Research Ethics Committee and NHS R&D Offices. An amendment will not be implemented without approval. Any deviation from the protocol, (including the nature and reason for deviation) will be documented and reported to the Chief Investigator and the study Sponsor. Any subsequent amendment will be submitted to the Sponsor for approval and then to the appropriate Research Ethics Committee and NHS R&D Offices for review and approval. If a serious breach of GCP is suspected, it will be reported to the Sponsor immediately using the 'Breach Report Form'.

9.1 Study record retention

Study records will be archived and stored on the University of Aberdeen's secure server (in the PACFIND restricted access folder) for a period of ten years.

9.2 End of study

The end of the study, defined as the last live online discussion of the last focus group, will be reported to the Sponsor and the Research Ethics Committee within 90 days of final data collection or within 15

days if the study ends prematurely. A summary report of the study will be provided to the Sponsor and Research Ethics Committee within one year of the end of the study.

10 DISSEMINATION POLICY

10.1 Dissemination policy

On completion, the findings of this study will be written up as a full report and made available on the PACFiND website and disseminated to key stakeholders, including public involvement groups working alongside the PACFiND study team and national charities such as Versus Arthritis and Fibromyalgia Action UK. We will offer all participants the opportunity to be sent a summary of the findings at the end of the study. In addition, the study findings will be presented at national and international conferences and disseminated through peer reviewed professional journals.

10.2 Authorship eligibility guidelines and any intended use of professional writers

Authorship of the final study report and subsequent papers for publication will follow guidance set out by The International Committee of Medical Journal Editors. Manuscripts will include acknowledgement of contributors and disclaimer statements as required by the funder.

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12. APPENDICIES

12.1 Required documentation

Letter of invitation to participants (v1 26.07.2020)

Participant information sheet observation &/or interview (v2 15th November 2020)

Participant information sheet online focus groups (v2 15th November 2020)

Information leaflet about observations (v2 15th November 2020)

Informed consent form observations (v2 15th November 2020)

Informed consent form interviews (v2 15th November 2020)

Informed consent form focus groups (v2 15th November 2020)

Observation record template (v1 5th October 2020)

Interview schedule (v1 5th October 2020)]

Outline focus group sample guide (v1 5th October 2020)

13. Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	2	15.11.2020	Nicky Wilson	Information about the limits of confidentiality in the event of the identification of safeguarding issues, poor standards of care or malpractice has been added to Section 8.5.