Study Protocol

CARDIOPHITNESS:

Cardiometabolic health and **Ph**armac**i**s**t**s in Severe Mental Ill**ness.**

VERSION CONTROL

Version number and date		Author	Next steps
v 1.0	04/04/2018	DS	Sent to Dr Ian Maidment, PhD Supervisor
v 1.1	11/05//2018	DS	Incorporated revisions: as suggested by supervisor, NIHR CRN East Midlands
v 1.2	22/06/2017	DS	Incorporated revisions; as suggested by project manager (research and knowledge exchange, Aston University)
v 1.3	04/07/2018	DS	Incorporated further revisions; as suggested by project manager (research and knowledge exchange, Aston University)
v 1.4	09/11/2018	DS	<u>Amendments as per Ethics review (24/10/2018 – 09/11/2018):</u> Amendments to circumstances under which care professionals will be offered £10 gift voucher <u>Amendments as per HRA review (04/10/2018)</u> Statement added to section 13.0 regarding arrangements for identifiable data (consent forms) to be transferred back to the NHS site.
v 1.5	30/12/2018	DS	<u>Amendments as per 1st year review at Aston University:</u> Inclusion criteria for participants to include patients with SMI who have cardiometabolic risk and/or metabolic syndrome and have had contact with pharmacy; carers who look after these patients. Include pharmacists as a separate group of participants.
	30.01.2019	DS	Methods and route of patient and care professional participants to include other activities: distribution of study material by R&D Lead for Leicestershire CCGs, People in Research platform, social media and newsletters.

Contents

1.0 Introduction

The **CARDIOPHITNESS** (**Cardio**metabolic health and **Ph**armac**ist**s in Severe Mental Ill**ness**) study is the second phase of a PhD exploring the role of pharmacy and pharmacists in the physical health of those with severe mental illness and is informed by an earlier literature review.

Mental illness accounts for around 23% of the total disease burden and leading cause of disability in the United Kingdom (1,2), and for significant health and social care costs (1, 2). A considerable fraction of these costs can be attributed to physical illnesses in people with severe mental illnesses (3). The definition of severe mental illness (SMI) encompasses schizophrenia, bipolar affective disorder, schizophrenia-like psychosis (e.g. schizophreniform and schizoaffective disorders) and other psychoses. Those with SMI have significantly higher rates of mortality and co-morbid physical ill health when compared to the rest of the population (4.5.6.7.8.9). Individuals with SMI die on average 20 years earlier than people without SMI (10). The underlying causes for this are both complex and multi-factorial (11).

The vast majority of these deaths are due to long term physical illness such as cardiovascular disease, cancer, respiratory disease and diabetes (6, 12, 13,14). There is a three-fold increase in the risk of death from coronary heart disease (8, 11), two-fold increased risk of diabetes (14, 15) and overall a ten-fold risk in death when compared to the general population (14,15).

Physical ill health in SMI may be due to a genetic predisposition, however, environmental factors and lifestyle factors such as poor diet, smoking, lack of physical activity and obesity/overweight play a prominent part (18). In addition for those with SMI there is inequity in access to medical care and quality of care. Additionally, health checks targeted at prevention are carried out less frequently in both primary and secondary care for those with SMI when compared with the general population (19-21). Studies have shown that those with SMI are just as motivated to make lifestyle change, in the case of smoking, can achieve cessation (22,23) In those with SMI the prevalence of obesity/overweight, smoking, poor diet, and lack physical activity is much higher; in England 40.5% of adults who have SMI are smokers (24) more than double that of the general population (15.5%) (25). Not only is diet poor (26,27) but levels of obesity (which range from 40-60%) are up to four times higher than the general population (28-30). Those with SMI are less physically active (31-33).

Unhealthy lifestyles and inadequate physical healthcare are also risk factors for dementia and Alzheimer's disease (34,35,36). Evidence suggests that vascular risk factor control can reduce a proportion of new cases of dementia, diabetes and CVD are risk factors can lead to the development of mild cognitive impairment, as well as dementia and Alzheimer's disease (36,37,38,39) . The rates of physical ill-health (mainly diabetes and hypertension) are also higher in older patients with dementia (39).

Adverse side effects of psychotropic medication include weight gain and obesity which subsequently increase the risk of diabetes and cardiovascular disease (CVD) (12, 40). Weight gain during acute and long term continuous treatment with antipsychotics is well-established adverse side effect (41, 42, 43) affecting 15-75% of patients (44). Antidepressants e.g. paroxetine and mood stabilisers e.g. valproate have also been associated with increased weight (42, 43). Antipsychotics can increase diabetes mellitus risk with the newer (so called atypical/second generation antipsychotics) having a stronger diabetogenic risk than the older (typical) antipsychotics (41, 42, 43). There also appears to

be an independent effect of antipsychotics contributing to CVD risk; individuals with SMI are three times more likely to experience sudden cardiac death compared to the general population (45,46).

'Medicines optimisation is defined as a person centred approach to safe and effective medicines use to ensure that people obtain the best possible outcomes from their medicines' (47). Medicines optimisation is an important consideration in those with SMI. Intolerable side effects are a significant contributor to non-adherence with psychiatric medications (48).

Metabolic side effects such as central obesity/weight gain, further contribute to lack of adherence (48, 49, 50). Research studies which investigate the role of support services for those with schizophrenia to improved medication adherence has yielded varying results (50). Pharmacists are experts in medication management and have knowledge, for example, about side effects, adverse drug reactions, screening and interpretation of blood tests, choice of medication and strategies to improve adherence as well as being an important part of the multidisciplinary team (51). In addition they can provide information, tools and signposting to facilitate positive lifestyle changes such as smoking cessation (52).

The views and perspectives of patients with SMI, their carers and care professionals are crucial in understanding the current and potential roles that pharmacy could play in the management of cardiometabolic risk factors, metabolic syndrome, diabetes, heart disease and related disorders. The research literature that does contains very limited amounts of qualitative information about the views and perspectives of key stakeholders on the role of pharmacy (53-63). This research study has been informed by a previous literature review on this topic; to our knowledge there is no published literature that investigates or explores patients', caregiving dyads or care professionals' perspectives of how they view and utilise pharmacy for support. In addition, nothing exists which attempts to triangulate the views of these key stakeholders on these issues. This study was therefore undertaken to address this gap.

Ultimately the aim is to reduce the inequalities in health that exist for individuals with SMI by improving the physical health of those with SMI. In this application I propose to examine in detail the role of pharmacy, pharmacists and to improve physical health in people with SMI.

2.0 Aims and objectives

The overall aim of this research programme of work is to explore the place and contributions of pharmacy in providing support and care (including lifestyle and medicines optimisation) for cardiometabolic risk factors and metabolic syndrome for individuals with SMI. This study had four main objectives:

1. To examine and understand the experiences and views of patients with SMI and their informal carers about care received for cardiometabolic risk factors, metabolic syndrome, diabetes, heart disease and related diseases;
2. To examine and understand how patients with SMI and their informal carers engage with activities in looking after and seek advice and support when needed for

cardiometabolic risk factors, metabolic syndrome, diabetes, heart disease and related diseases;

3. To explore the views of patients with SMI and their informal carers on whether and how they utilise pharmacy for care and support for cardiometabolic risk factors, metabolic syndrome, diabetes, heart disease and related diseases;
4. To explore the views and experiences of care professionals on providing care for cardiometabolic risk factors, metabolic syndrome, diabetes, heart disease and related diseases; as well their views on pharmacy and pharmacists providing this care.

3.0 Study design

An exploratory qualitative study design that will follow Consolidated Criteria for Reporting Qualitative studies (COREQ) guideline will be employed (64). This will be undertaken using semi-structured interviews where participants provide a detailed account of their views guided by an interview schedule. The setting will be in both primary care and secondary care in the UK. The target population are individuals aged 18 and over with SMI, informal carers of those with SMI and care professionals directly involved in their care.

4.0 Overview of recruitment strategy

Patients with SMI	Informal carers of individuals with SMI.	Care professionals who are directly involved in the care of those with SMI.
Indirect Poster (Appendix 14) • displayed in site reception areas • sent to SMI patient support groups • sent to research manager at LPT NHS Trust who will contact SMI patients via EPPIC • Display the opportunity on People in Research platform https://www.peopleinresearch.org/ • Other patient and public involvement activities including social media and newsletters *(The EPPIC (Embedding Patient and Public Involvement Collaboration)) project is a service development initiative for research and development in LPT NHS Trust.	**Direct** • When face to face interviews take place with individuals with SMI they will be given an information pack about the study to hand to their nominated informal carer. The information pack will contain a letter of invitation (Appendix 7) and carer PIS (Appendix 8) • The nominated informal carer should be someone who the individual with SMI identifies as the person they get most support from.	**Indirect** Poster (Appendix 14) • Sent to NIHR CRN East Midlands for distribution to primary care professionals. • Sent to R&D department of Leicestershire Partnership NHS Trust for distribution to mental health professionals in secondary care, via global email, weekly e-newsletter and as an attachment to their postgraduate education session timetable • Send to R&D Lead for Leicestershire CCGs for distribution to GP practices and other care professionals within the CCGs
&		&
Direct • LPT NHS Trust (Mental health trust) to identify patients who meet eligibility criteria through reporting systems and team leader/care coordinators/consultants provide those patients with a letter of invitation (Appendix 1) and patient PIS (Appendix 2) • NIHR CRN East Midlands and the R&D Lead for Leicestershire CCGs who will contact GP surgeries and send them an introductory letter. (Appendix 12). Interested practices will identify patients who meet the eligibility criteria through reporting systems and post out letter of invitation (Appendix 1) and patient PIS (Appendix 2) to these patients. In addition opportunistic recruitment will be undertaken by the GP surgeries (poster will be given to eligible patients).		**Direct** Lead researcher to ask LPT NHS Trust Senior Pharmacist/Pharmacy manager to send out email (Appendix 13) and poster (Appendix 14) to: • Team leaders/consultants within LPT NHS Trust LPC and ask them to forward to their community pharmacist members • Medicines optimisation pharmacist lead for each CCG for distribution to their pharmacists • The lead for the College of Mental Health Pharmacists so they can contact their members via appropriate channels • Pharmacy team at the NHS trust (by pharmacy manager) Also other professional contacts as appropriate
↓		↓
Reminder: 2-4 weeks later		Reminder:2-4 weeks later
↓	↓	↓
For those individuals who contact the lead researcher	**For those individuals who contact the lead researcher**	**For those individuals who contact the lead researcher**
Eligibility screening: screen for eligibility and assess capacity for participation. Answer any questions or queries. Send out letter of invitation (Appendix 1) and patient PIS (Appendix 2) where appropriate.	**Eligibility screening**: screen for eligibility and assess capacity for participation. Answer any questions or queries. Send out letter of invitation (Appendix 7) and carer PIS (Appendix 8) where appropriate.	**Eligibility screening**: screen for eligibility Answer any questions or queries. Send out and letter of invitation (Appendix 4) and care professional PIS (Appendix 5) where appropriate.
↓	↓	↓
Follow up – arrange interview	**Follow up – arrange interview**	**Follow up – arrange interview**
↓	↓	↓
Written informed consent. Formal consent processes undertaken including signing consents for participation	**Written informed consent.** Formal consent processes undertaken including signing consents for participation	**Written informed consent.** Formal consent processes undertaken including signing consents for participation
↓	↓	↓
Enrolment and data collection. Time location for interview arranged. Conduct interview as soon as possible after enrolment	**Enrolment and data collection.** Time location for interview arranged. Conduct interview as soon as possible after enrolment	**Enrolment and data collection.** Time location for interview arranged. Conduct interview as soon as possible after enrolment
Decline at any point. Patient to withdraw no further action	**Decline at any point.** Informal carer to withdraw no further action	**Decline at any point.** Care professional to withdraw no further action

5.0 Individuals with SMI

5.1 Inclusion criteria

- Aged 18 years or over. No upper age limit.
- A diagnosis of schizophrenia, bipolar disorder, schizoaffective disorder or other non-organic psychosis (ICD-10 codes F10.5, F11.5, F12.5, F13.5, F14.5, F15.5, F16.5, F19.5, F20-29, F30.2, F31.2, F31.5, F32.3 and F33.3) which has been given to them by mental health/psychiatric services **or** SMI patient support group member
- Have a cardiometabolic risk factor and/or metabolic syndrome
- Have had support from pharmacy
- With capacity to provide informed consent to participate in the study.

5.2 Exclusion criteria

- Individuals with SMI under the age of 18.
- Non-English speaking.
- Lack of capacity to consent.

5.3 Recruitment

Individuals with SMI will be recruited using several methods to maximise participation. Methods will be employed to avoid inadvertent targeting of individuals who do not meet the inclusion criteria. These methods will include displaying the poster (Appendix 14) at site reception areas (e.g. reception area of mental health community outpatient department); the poster (Appendix 14) will also be sent to SMI patient support groups and to the research manager at LPT NHS Trust who will contact patients via EPPIC – the EPPIC (Embedding Patient and Public Involvement Collaboration) project is a service development initiative for research and development in LPT NHS Trust.

The lead researcher will arrange a meeting with R&D team at LPT NHS Trust.

- The research study will be discussed at this meeting.
- The lead researcher will request a targeted approach to recruiting at this meeting: they will request that the R&D team contact the Business Information Manager in the Performance and Information department of LPT NHS Trust.
- The Business Information Manager will generate a list of patients who meet the eligibility criteria (from electronic record systems) and then send this list to the R&D team.
- The R&D team will then send this list of patients to team leaders/care coordinators/consultants who will then provide each of their patients on this list with a patient participant information sheet (PIS) (Appendix 2) and letter of invitation (Appendix 1)

The lead researcher will arrange a meeting with the NIHR CRN East Midlands and the R&D Lead for Leicestershire CCGs. The research study will be discussed at this meeting. The CRN and the R&D Lead for Leicestershire CCGs will contact GP surgeries with an introductory letter (Appendix 12) asking if they are interested in takin part and identify patients who meet the eligibility criteria. The surgery will be contacted 2-4 weeks later to follow up and if they are willing to take part they will be sent prepaid envelopes containing copies of a

patient PIS (Appendix 2) and letter of invitation (Appendix 1); these will be sent out in the post to the patients identified by the GP surgery. In addition opportunistic recruitment will be undertaken by the GP surgeries (poster will be given to eligible patients when they are seen by care professionals e.g. GP consultation). We may also recruit individuals with SMI who became aware of the study via our PPI (patient and public involvement) engagement activities e.g. via mental health charities such as Bipolar UK blogs, patient group meetings etc. and voluntarily offer to participate in the study. This will include displaying the opportunity on People in Research platform https://www.peopleinresearch.org/. Other patient and public involvement activities including social media and newsletters

5.4 Eligibility screening and consent

(1) Only potential participants who have contacted the lead researcher using the contact details provided on the poster, invitation letter or PIS will be contacted.
(2) The lead researcher will contact the potential participant to discuss the study and answer any questions they may have before checking their eligibility. This will include asking them if they have (a) a diagnosis (from mental health/psychiatric services) of schizophrenia, bipolar disorder, schizoaffective disorder or other non-psychotic disorder and (b) any of the following: cardiometabolic risk factors and/or metabolic syndrome including smoking, overweight/obese, weight gain, high blood pressure, hypertension, medication for high blood pressure, raised blood glucose, diabetes, heart disease or abnormal blood lipids and (c) have had support from pharmacy.
(3) For those confirming they meet the criteria outlined in (2) above and who are still interested in participating the following documentation then an information pack will be sent out (letter of invitation (Appendix 1) and patient PIS (Appendix 2)) if they haven't received these already. If there has been no response after two weeks from those individuals sent the information at this point the lead researcher will make follow up contact with the potential participant.
(4) Individuals who self-report a diagnosis of SMI but have not had contact with mental health or psychiatric services (this may occur if recruited via the poster) will be provided with information about such services and directed to contact them as appropriate. These individuals will be thanked for expressing an interest in the study but informed that they are not eligible to take part.
(5) A face-to-face appointment will be arranged to carry out the interview at a mutually convenient time and venue.
(6) When the lead researcher meets the potential participant face-to-face, capacity to consent will be undertaken and they will be given the opportunity to ask additional questions about the study.
(7) They will be reminded that although the interview will be digitally recorded (using an encrypted digital recorder) all information they disclose is confidential and their name will not be used in any quotations in written reports, publications or presentations.
(8) The lead researcher will then reimburse the participant for any reasonable out of pocket and travel expenses and also offer a £10 gift voucher as a sign of appreciation for participation in the interview. The researcher will advise the potential participant that taking part is entirely voluntary and that it will not affect the care they receive from the NHS and that they are free to withdraw at any time without providing a reason. They will be informed that they have until the point at which their data is anonymised to withdraw all or any of the information provided or discussed in the interview.

(9) Once written informed consent has been obtained (Appendix 3) a short background information questionnaire (for demographic data and clinical data) (e.g. diagnosis) will be completed with the participant before commencing the interview.

5.5 Interviews

Interview topic guide (Appendix 9) have been prepared prior to the semi-structured interviews to guide data collection and to guide and focus discussion, however the interviews are were flexible and participants were able to discuss any relevant issues and to reflect. All interviews will be audio-recorded and transcribed verbatim. In addition hand written notes will be taken during each interview to record any important observations and after the interviews to record any additional statements as well as the researcher's reflection of the interview. Each interview participant will be allocated an identification code, which will be used on all documentation (including background questionnaire) and transcripts relating to an individual participant. We will keep anonymised transcripts/handwritten notes taken during interviews. Original audio recordings will be destroyed.

6.0 Informal carers of individuals with SMI

6.1 Inclusion criteria

This person will be identified by a participant with SMI as the person (who is not a care professional) they get most support from, not necessarily a family member.

- Adults aged 18 years and over. No upper age limit.
- An informal carer for a patient recruited to the study. This person will be identified by the patient as the person (who is not a care professional) they get most support from, not necessarily a family member)
- With capacity to provide informed consent to participate in the study

6.2 Exclusion criteria

- < 18 years old
- Non-English speaking
- Lack of capacity to consent

6.3 Recruitment

Methods will be employed to avoid inadvertent targeting of individuals who do not meet the inclusion criteria. The aim of the recruitment strategy is to recruit caregiving dyads. When face to face interviews take place with individuals with SMI they will be given an information pack about the study to hand to their nominated informal carer. The information pack will contain a letter of invitation (Appendix 7) and carer PIS (Appendix 8).

6.4 Eligibility screening and consent

(1) Only informal carers who have made contact with the lead researcher using the contact details on the letter of invitation or carer PIS will be contacted.

(2) The lead researcher will contact the potential participant to discuss the study and answer any questions they may have before checking their eligibility. This will consist of asking them if are an informal carer providing the care for someone with a diagnosis of schizophrenia, bipolar disorder, schizoaffective disorder or other non-psychotic disorder. If necessary letter of invitation and carer PIS will be sent out.
(3) They will be asked to identify the patient recruited to the study from whom they received the information pack from. The unique participant identification number of that patient recruited will be retrieved and this number will be noted alongside the informal carers unique participant identification number to allow for the lead researcher to link the data during the data analysis process.
(4) For those individuals who meet the inclusion criteria and are still interested in participating, a face-to-face appointment will be arranged to carry out the interview at a mutually convenient time and venue.
(5) When the lead researcher meets the potential participant face-to-face, capacity to consent will be undertaken and they will be given the opportunity to ask additional questions about the study.
(6) They will be reminded that although the interview will be digitally recorded (using an encrypted digital recorder) all information they disclose is confidential and their name will not be used in any quotations in written reports, publications or presentations.
(7) The lead researcher will then reimburse the participant for any reasonable out of pocket and travel expenses and also offer a £10 gift voucher as a sign of appreciation for participation in the interview. Finally, before written consent is provided the researcher will advise the potential participant that taking part is entirely voluntary and that it will not affect the care that the person they care for receives from the NHS (if relevant) and that they are free to withdraw at any time without providing a reason. They will be informed that they have until the point at which their data is anonymised two weeks after the interview to withdraw all or any of the information provided or discussed in the interview.
(8) Finally written informed consent (Appendix 3) will be obtained. Once written consent has been obtained the participant a short background information questionnaire (for demographic data) will be completed with the participant before commencing the interview.

6.5 Interviews

Interview topic guide (Appendix 11) have been prepared prior to the semi-structured interviews to guide data collection and to guide and focus discussion, however the interviews are were flexible and participants were able to discuss any relevant issues and to reflect. All interviews will be audio-recorded and transcribed verbatim. In addition hand written notes will be taken during each interview to record any important observations and after the interviews to record any additional statements as well as the researcher's reflection of the interview. Each interview participant will be allocated an identification code, which will be used on all documentation (including background questionnaire)) and transcripts relating to an individual participant. We will keep anonymised transcripts/handwritten notes taken during interviews. Original audio recordings will be destroyed.

7.0 Care professionals

7.1 Inclusion criteria

- Care professionals who are directly involved in the care of individuals with SMI who have a cardiometabolic risk factor and/or metabolic syndrome and who have had support from pharmacy.

7.2 Exclusion criteria

- Care professionals who are not directly involved in the care of individuals with SMI.

7.3 Recruitment

- Poster (Appendix 14) will be sent to NIHR CRN East Midlands and R&D Lead for Leicestershire CCGs and for distribution to GP practices
- Poster (Appendix 14) will be sent to the R&D department of Leicestershire Partnership NHS Trust for distribution to mental health professionals via mechanisms including global email, NHS Trust e-newsletter and as an attachment to their postgraduate education session timetable.

Lead researcher to ask LPT NHS Trust Senior Pharmacist/Pharmacy Manager to send out email (Appendix 13) and poster (Appendix 14) to:

- team leaders/consultants within LPT NHS trust;
- LPC and ask them to forward to their community pharmacist members
- Medicines optimisation pharmacist lead for each CCG for distribution to their pharmacists;
- The lead for the College of Mental Health Pharmacists so they can contact their members via appropriate channels;
- Pharmacy team at the trust (by a pharmacy manager).

We will also recruit via other professional contacts as appropriate.

7.4 Eligibility screening and consent

(1) Only care professionals who have made contact with the lead researcher using the contact details on the poster will be contacted.
(2) At this point the lead researcher will contact the potential participant to discuss the study and answer any questions they may have before checking their eligibility. This will consist of asking them if they are a care professional directly involved in the care of an individual who has a diagnosis of schizophrenia, bipolar disorder, schizoaffective disorder or other non-organic psychosis and that the person they care for has a cardiometabolic risk factor and/or metabolic syndrome and has had support from pharmacy.
(3) For those confirming they meet the criteria outlined in (2) and who are still interested in participating the following documentation: then be sent out: letter of invitation (Appendix 4) and care professional PIS (Appendix 5). Any potential participants who reveal they do not meet the inclusion criteria will be thanked for

expressing an interest in the study, but informed that they are not eligible to take part.

(4) If there has been no response after two weeks the lead researcher will make follow up contact with the potential participant
(5) A face-to-face appointment will be arranged to carry out the interview at a mutually convenient time and venue.
(6) They will be reminded that although the interview will be digitally recorded (using an encrypted digital recorder) all information they disclose is confidential and their name will not be used in any quotations in written reports, publications or presentations.
(7) The lead researcher will offer a £10 gift voucher as a sign of appreciation for participation in the interview if they take part in their own time. The care professional will not be offered a £10 gift voucher if they part in the study during their work time. Finally, before written consent is provided the researcher will advise the potential participant that taking part is entirely voluntary and that they are free to withdraw at any time without providing a reason. They will be informed that they have until the point at which their data is anonymised to withdraw all or any of the information provided or discussed in the interview.
(8) Finally written informed consent (Appendix 6) will be obtained. Once written consent has been obtained the participant a short background information questionnaire (for demographic data) will be completed with the participant before commencing the interview

7.5 Interviews

Interview topic guide (Appendix 10) have been prepared prior to the semi-structured interviews to guide data collection and to guide and focus discussion, however the interviews are flexible and participants will be able to discuss any relevant issues and to reflect. All interviews will be audio-recorded and transcribed verbatim. In addition hand written notes will be taken during each interview to record any important observations and after the interviews to record any additional statements as well as the researcher's reflection of the interview. Each interview participant will be allocated an identification code, which will be used on all documentation (including background questionnaire) and transcripts relating to an individual participant. We will keep anonymised transcripts/handwritten notes taken during interviews. Original audio recordings will be destroyed.

8.0 Sample size

The sample size will not be informed by a formal statistical power calculation. Purposive sampling will be used to seek information-rich cases which capture core themes and are representative of the general population. The sample size will be up to 30 people with SMI, up to 30 informal carers, up to 30 care professionals and up to 30 pharmacists. The exact number will be determined by the point of data saturation when it appears that no new substantive themes are identified in the data. The sample size will not be informed by a formal statistical power calculation.

9.0 Data analysis

A table summarising the demographic (and in the case of patients, clinical) data (using unique patient identification numbers) will be produced to provide an overview of the population of each group studied. A qualitative framework analysis will be undertaken in

order to explore the experiences and perspectives of the participants using an open-coding method [65, 66, 67]. Framework analysis is a tool that has no allegiance to either inductive or deductive thematic analysis; this research will be both deductive and inductive [68]. Each transcript will be read and coded separately using Nvivo software if considered appropriate. Common themes will be merged to create categories, enabling analysis of data to reflect recurring and representative themes [38]. Validity will be increased by actively seeking deviant cases and outliers [65]. The analysis of the different strands of qualitative data will be informed by an ongoing review of the literature [69]. However, where appropriate the data analysis and interpretation will be informed by wider relevant literatures, for example theories relevant to preventative healthcare use. Data analysis will therefore be exploratory and will include substantial Third sector and PPI consultation to enrich the discussion with my supervisory team.

10.0 Research Governance

The study will be conducted to protect the human rights and dignity of the participant as reflected in the 1996 version of the Helsinki Declaration**.**

Reasonable out of pocket and travel expenses associated with participating in the research (e.g. attending an interview) will be reimbursed for patients and carers and participants will also be offered a £10 gift voucher as a sign of appreciation for participation in the interview (this will be offered in all cases for patients and carers but only for care professionals if they participate in their own time not in their work time). This is line with INVOLVE guidance.

11.0 Study sponsorship

Aston University will act as sponsor for the CARDIOPHITNESS Study.

12.0 Ethical issues and approval

Ethical approval will be obtained from the HRA.

13.0 Data storage and confidentiality

Interviews will be recorded using an encrypted digital recorder. All data will be stored in accordance with data protection requirements. Printed copies and consent-related documents will be stored in a site file, which will be kept in a locked filing cabinet within the LPT NHS Trust. All electronic data will be stored on password protected NHS computers and laptop and backed up on a secure NHS server. Only the lead researcher will have access to the data. (A study master file will be kept at Aston University - however, this will not contain any patient identifiable information).

Consent will be undertaken immediately prior to the interviews being conducted. As such in all cases this will be done by the lead researcher who will be carrying out the interviews. Once the interview has been completed the consent forms will be taken to the pharmacy department within LPT NHS Trust and stored in locked filing cabinets.

A summary of the findings of the research will be available on completion of the study on the following webpage. This will not contain any identifiable information.

http://www.leicspart.nhs.uk/_InvolvingYou-CardioPhitnessResearchStudy.aspx

14.0 Informing participants of anticipated risks and benefits.

All participants will be sent a participant information sheet, which will inform them about the potential benefits and risks of taking part.

Chief Investigator signature: ……..

Date:……

15.0 References

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16.0 Appendices

- Appendix 1 – Letter of invitation to Patients
- Appendix 2 – Participant information sheet - patient
- Appendix 3 – Participant consent form – patient/carer
- Appendix 4 – Letter of invitation to care professionals
- Appendix 5 – Participant Information sheet - care professionals
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- Appendix 8 – Participant Information sheet (informal carers)
- Appendix 9 – Topic Guide for interview with patients
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- Appendix 12 – GP practices/GP lead introductory letter
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