Title: Patient Centred Assessment Method (PCAM): improving nurse led biopsychosocial assessment of patients with long term conditions and co-morbid mental health needs.

Summary of Research

Background: Recent Quality and Outcomes Framework (QoF) initiatives to promote primary care led assessment of mental health problems in people living with long term conditions (LTCs) did not have the intended impact (1-3). This may be due to the limited experience and lack of confidence of primary care nurses who conducted most depression screening within routine annual reviews. The tick box and medicalised nature of the QoF only served to limit these skills even further (4) and contribute to little or no attention being paid in these assessments to the social problems that might contribute to poor physical and mental well being. The Patient Centred Assessment Method (PCAM) has been developed to enable broad assessment of patient biopsychosocial needs in primary care and to promote action based on the severity and urgency of needs. The PCAM is an adapted version of the Minnesota Complexity Assessment Method which was derived from the INTERMED (5-7). The PCAM has previously been evaluated, and continues to be used, in anticipatory (Keep Well) health check clinics in Scotland (8) but has not been evaluated for use by primary care practice nurses and its potential value for addressing mental well-being in patients with LTCs. Neither has it been subject to clinical trial to determine its impact on nurse behaviour and patient outcomes.

Research questions: Is it feasible and acceptable to use the PCAM in primary care nurse led annual reviews for those with LTCs? Is it feasible and acceptable to run a cluster randomised trial of the PCAM intervention in primary care?

Aim: This research will assess the acceptability and implementation requirements of a tool (PCAM) for enhancing the care of patients with LTCs and co-morbid mental and social care needs in primary care. It will also assess fidelity of its implementation/use amongst nurses, and will include a feasibility trial in preparation for a future full scale trial of its impact/effectiveness on nurse-delivered patient care and patient outcomes.

Methods: Primary care professionals and people with LTCs will assess the acceptability and implementation requirements of the PCAM (especially for nurse consultations for LTCs). This will be conducted via practitioner and patient focus groups. The PCAM will then be tested in a feasibility cluster randomised controlled trial in 8 GP practices, involving 16 practice nurses (2 per practice). Four practices (8 nurses) will be allocated to deliver the PCAM intervention and 4 practices (8 nurses) will deliver care as usual. Baseline data collection will be conducted in all practices with all study nurses prior to randomisation and will consist of immediate post consultation data collection for a cohort of 10 patients per nurse (n=160 patients) including: patient demographics, patient completed evaluation of consultation and patient completed outcome measures; and any Nurse referrals or signposting to services during consultation. Patient completed outcome measures will also be collected by postal questionnaire at 8 weeks follow-up. Practices will then be randomised to the PCAM intervention or to deliver care as usual. The same data will be collected for a second cohort of patients in both intervention and control practices (n=160 patients) following the introduction of the PCAM in intervention practices. The second cohort will also complete follow-up measures at 8 weeks.

Fidelity of implementation and an understanding of how nurses use the PCAM, and whether it changes how they engage in assessments will be tested via a sample of audio recorded nurse led annual assessments both pre (n=5 per nurse) and during use of the PCAM (n=5 per nurse). Follow-up interviews with nurses and patients will reflect on use and perceived impact of PCAM.

Outcomes: primary outcome will be estimates of recruitment and retention of nurses, and patient consent and completion of questionnaires including follow-up completion rates. Patient outcomes tested for use in a future trial are the General Health Questionnaire-12 (GHQ-12)(9), Short Form -12 (SF12) (10), and the Warwick and Edinburgh Mental Well Being Scale (WEMWBS) (11). Nurse behaviour is measured via: the number and types of referrals/signposting; patient evaluation of nurse consultations via the Consultation and Relational Empathy (CARE) measure (12), and the Patient

Enablement Instrument (PEI) (13); and nurse confidence in dealing with mental health issues using the Depression Attitude Scale (DAS)(14).

Analysis: comparison of intervention and control recruitment, retention and follow-up data completion. Establishment of best primary and secondary outcomes for main trial. Qualitative analysis using NVivo will focus on barriers and facilitators and draw on Normalisation Process Theory(15).

Background and Rationale

Over 15 million people in the UK (2 million in Scotland) report living with a long term condition (LTC) with an estimated 6.5 million living with more than one, and these numbers are projected to keep rising over the next decade (16). Chronic physical illnesses are associated with increased prevalence of depression (17). Until recently, expert guidelines recommended screening for depression in patients with Diabetes Mellitus (DM) and Coronary Heart Disease (CHD); however research found only little or no impact of screening on the recognition of depression in these patients (1-3). Screening was mostly carried out, without training, by nurses as part of annual LTC reviews. Recent research has highlighted problems with nurse engagement in 'screening' and how the 'tick box' approach of the Quality and Outcomes Framework (QOF) might have led to under-detection of depression in LTC patients (4). Previous studies have also found that practice nurses recognized only 16% of psychologically distressed patients attending their clinics. (18).

It is well accepted that deprivation and physical and mental health are closely linked, with an understanding that a broad range of stressors, more common in deprived communities, can negatively impact the physical and mental health of people. A recent study of multimorbidity has found that 42·2% of all patients had one or more morbidities, and 23·2% were multimorbid. Onset of multimorbidity occurred 10–15 years earlier in people living in the most deprived areas compared with the most affluent, with socioeconomic deprivation particularly associated with multimorbidity that included mental health disorders (prevalence of both physical and mental health disorder). The presence of a mental health disorder increased as the number of physical morbidities increased, and was much greater in more deprived than in less deprived people (19). Broader social and economic conditions influence both the incidence and success in treating many conditions (20), including patient engagement in self care practices which are essential in LTCs. The Patient Centred Assessment Method (PCAM) is one approach that has been developed to help professionals assess and respond to a broader range of health related needs but has not been tested for use in UK primary care (7,8). It has been evaluated in anticipatory health checks in Scotland (8). This research will determine whether the PCAM can be used by primary care nurses to improve the quality of care for patients and whether it is feasible and worthwhile conducting a future effectiveness trial of this tool to improve quality of care, holistic assessment of needs and promote access to wider health and community based services. PCAM will also provide a much needed systematic process for measuring and assessing the broader biopsychosocial needs of patients, which will help quality improvement initiatives by contributing novel and important metrics.

The findings of this research will be used to inform whether a future full scale RCT is feasible and the methods proposed are acceptable and to develop a research protocol and application for funding for such a trial. It will also inform whether the PCAM is acceptable for use in primary care, primarily for conducting reviews of people living with LTCs who are at greater risk of mental health and social problems, and for its potential role in improving holistic assessment and care more generally for patients living in areas of high deprivation who are in greater need of health and social interventions. There is potential for nurses to be re-skilled in patient engagement and to be able to identify when and what type of help is required, when patients are ready to engage in more self care activity, and what barriers there might be to self care activity. It is hoped that wider demonstration of the effectiveness of the PCAM will transform how primary care engages with patients and their needs. It is also hoped that it will result in greater integration of health and social care needs and the coordination of meeting these needs and that use of the PCAM will result in greater use of community and voluntary sector resources as was demonstrated in the Keep Well evaluation in Scotland. Such actions will reduce the current burden on 'NHS only' use of services in the management of LTCs.

The current mechanisms within the NHS for encouraging self care practices fail to acknowledge the barriers that are created through many patients' disadvantaged lives. This often includes reduced health literacy which will require a different type of input if self caring behaviours are to be understood

and accommodated within difficult lives. Again, attention to recognising and addressing these broader needs and organising responses which other sectors are better positioned to meet will ensure more efficient use of NHS resources. Such an approach is endorsed by the RCGP in its report 'The 2022GP: A vision for General Practice in the Future NHS' where one of the first recommendations is about strengthening links between general practice and communities.. The proposed PCAM tool can support making and strengthening such links as it encourages nurses' signposting to local (non medical) resources. Two of our team members (SM and CHoy) are involved in the Improving Links in Primary Care project which is a partnership between the RCGP and the Health and Social Care Alliance and the Access to Local Information to Support Self management for people with long term health conditions project (ALISS).

A small evaluation of the potential of PCAM for use in highly vulnerable populations showed that it was perceived as having strong advantages in better managing the needs of homeless and travelling populations (8). If PCAM is shown to improve the care of people living in highly deprived communities it could have real advantages for addressing health inequalities. The PCAM may also provide a more systematic approach for primary care in responding to the NICE recommendations for depression within the new QOF which include biopsychosocial assessment of all patients with depression.

Evidence explaining why this research is needed now

Over 15 million people currently report living with a LTC in the UK, and numbers are projected to keep rising over the next decade. People with LTCs account for: 50% of GP appointments (80% in Scotland); 70% of inpatient bed days; and 70% of the total health and care spend in England (21,22). People with multiple morbidity utilise more healthcare resources including increased hospital bed occupancy (23). Improving the management of LTCs has the potential to both reduce hospital bed occupancy and improve the quality of life for this group of patients (24). Those living in a deprived area are more than twice as likely to have a LTC compared with those living in more affluent areas. People with LTCs are also more likely to be disadvantaged across a range of social indicators (25). Living with these conditions can result in additional acute and chronic stress, increasing the risk of anxiety and depression, which can in turn further impact on their physical health and ability to self care.

Supporting People with Long Term Conditions (DoH, 2005) based its improvement programme on models from the USA (Kaiser Permanente; Pfizer; and Evercare). These models are based on nurses acting as case managers, who have a key role in coordinating services from other health and social care providers (26). However, in primary care, this ideal has moved little beyond nurses conducting annual health checks that meet the requirements of the QOF. The RCGP promotes Care Planning (27) but acknowledge that co-existing mental and social circumstances may prevent such approaches. The RCGP response to QOF indicators for depression noted that "a holistic assessment should be part of the routine management of any patient with a long term condition". There are few validated tools for such assessment, especially for use by nurses. The development of interventions for primary care that encourage holistic assessment and action to address complex health and social needs is urgently required.

This research will determine whether the PCAM tool can be used by practice nurses to engage in holistic assessment of patient's needs in those with LTCs, and particularly for those with multiple and complex needs. This tool encourages action to be taken based upon the severity and urgency of the patient's situation. Its use encourages a dialogue between the healthcare practitioner and the patient which serves to re-skill the practitioner in providing patient centred holistic care; as opposed to the de-skilling which has been reported by nurses through the 'tick box' mechanisms to improve quality of care.

The PCAM will help to identify and address some of the broader social problems which often lead to or exacerbate poor mental health, which can in turn impact on physical health and the patient's ability to self care. It encourages linking with other sectors to more appropriately address these problems for patients and to access alternative types of resources.

Engaging in health promoting behaviour and self care practices can be limited or even impossible when adverse social circumstances intervene. Attention to these (often patient priorities) could lead to improvements in patients' abilities to subsequently engage in self care and achieve the benefits that

the Department of Health have long anticipated with increased self care practices (less use of healthcare resources, better quality of life, and reduced mortality). The PCAM also encourages new ways of working that enhance opportunities for health promotion - even in those with few current health or social problems, to maintain healthy behaviour. This will lead to improved quality of life for patients and better patient/professionals interactions and relationships.

The previous mechanism for ensuring attention to mental health needs of people with LTCs (QOF depression screening) did not prove to be beneficial in this respect. Depression screening in LTCs has now been removed from the QOF but patient and carer groups argued this would only serve to remove the imperative to include assessing mental health needs in LTCs. NICE now recommend a biopsychosocial assessment is carried out, but only for patients newly diagnosed with depression, and provide little guidance on how this should be addressed and no imperative to act on this assessment (28). This study could provide some much needed knowledge around how this could be conducted in primary care and the intended trial could provide evidence of the effectiveness of this new QOF recommendation.

This tool provides an alternative approach to assessing health needs which includes a biopsychosocial assessment for all patients with LTCs which will more likely lead to accessing social supports to both prevent the development of mental health problems or to address these in their early stages with self help (less medicalised) strategies. It still encourages the need to seek further professional help when severity and urgency dictate (e.g. for clinical depression). This research builds on a small evaluation of the PCAM funded by NHS Health Scotland to improve assessment of mental health and social needs within anticipatory health checks. Within this study, the use of PCAM was also explored in an 'access' practice serving homeless and travelling populations. It was deemed to be a valuable tool for helping assess and address some of the needs of the most vulnerable of society.

Aims and objectives

Aims:
To assess the acceptability and implementation requirements of the Patient Centred Assessment Method (PCAM) for use in UK primary care, particularly with practice nurses in the context of annual reviews for people with LTCs
To examine fidelity of use of PCAM by practice nurses in routine annual reviews of LTCs
To assess the feasibility of conducting a full-scale trial of effectiveness of the PCAM based on 2 potential units of analysis, namely intermediate level nurse behaviour and longer term patient wellbeing. The pilot trial will answer the following questions:

- Can we recruit and retain practices and nurses to take part in the study?
- Can they implement study procedures correctly?
- Are patients willing to complete questionnaires/outcome measures?
- How much missing data are there and does this relate to nurse or patient level follow-up?
- What estimates of effect size, variance and likely intra cluster correlation should be used to inform the sample size of the full study? Should the unit of analysis be at nurse or patient level or is it feasible or necessary to include both?

Objectives:
To conduct focus groups with primary care staff and patients with LTCs to assess acceptability and implementation requirements.
To conduct a cluster RCT in 8 practices and with 16 nurses to test the acceptability and feasibility of running a full scale trial of the PCAM in primary care.
To examine the fidelity of nurse use of the PCAM via a sample of audio-recorded consultations pre and during implementation.
To explore nurse and patient perceptions of using the PCAM in annual reviews for LTCs.
To conduct a process evaluation to identify possible contextual influences on study implementation.

The PCAM (formerly known as the Minnesota and Edinburgh Complexity Assessment Method MECAM) was derived from ‘INTERMED’, which was developed for use in acute settings. The INTERMED assessed biopsychosocial aspects of the patient and how they related to the healthcare system which, taken together, reflect ‘case complexity’ (5-7). The purpose of PCAM was to provide a

practical but systematic vocabulary and action-based evaluation system which could be applied to a primary care setting to improve the care, and self care, of patients with multiple (complex) needs. An early version, the Minnesota Complexity Assessment Method (MCAM) was developed in the USA for use by clinical teams (doctors and nurses) for the case management of patients with medically unexplained symptoms (7). While the conceptual basis for assessing complexity has been established via the INTERMED and MCAM, further adaptation and validation was required for use in a UK health context. This has been undertaken by the current team but in the context of adapting it for use in Keep Well health screening consultations. This has resulted in the development of the Patient Centred Assessment Method (PCAM) as an adapted version of the MCAM for use in the UK. It was successfully implemented and evaluated with 7 Keep Well nurses and was shown to increase onward non-medical referrals, especially to psychological, social and lifestyle referrals. Current roll-out of its use in NHS Lanarkshire has been reported by the service lead to be making 'a real difference' to nurse engagement with the mental and social wellbeing of patients.

It is therefore a reasonable theoretical assumption that the PCAM could be of value for primary care nurse engagement with the mental and social well-being of their patients with LTCs who are at higher risk of poor mental health and social problems. However, the 'Keep Well' context is not entirely comparable to routine primary care. These were anticipatory health checks among 'at risk' populations with longer time available at each consultation. The tool has not been reviewed by GPs or practice nurses, nor has its usability and acceptability been evaluated in primary care. Furthermore, there has been no patient in-put to use of the tool. This study will assess its acceptability and implementation requirements for use with practice nurses and establish whether a trial is worthwhile.

Research Plan / Methods

Theoretical/conceptual framework

The conceptual models used to consider how to address LTCs has been influenced by the Chronic Care Model (CCM) (29), however this model has been critiqued for failing to articulate in greater detail what the community resources aspect of the model could consist of (30, 31). While the CMM provides a comprehensive and well tested model, it suggests that the 'informed, activated patient' somehow sits outside of the broader social influences of the community and health system. Yet research on LTCs shows a compelling link with broader social determinants of health, and finding way to make these social determinants and patient experiences more central to the conceptual model could be useful. This would re-emphasize the role of broader social determinants not as outside influences on the interactions between patients and providers, but as a key part of patient's overall experience of becoming unwell, and living with a long term condition. Finding ways to facilitative the productive interactions throughout all levels of the experience of patient and providers then becomes the methodological challenge to adapting the CMM to a model that integrates the social determinants of health which are so central to the experience of patients living with LTCs. This research will test the role of PCAM in furthering our conceptual frameworks used to understand the care and experience of patients living with LTCs.

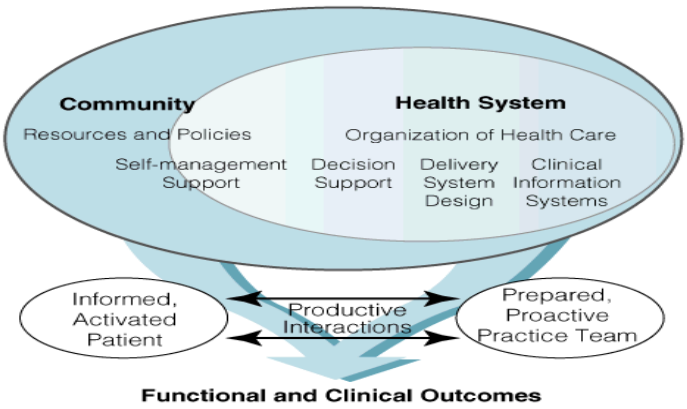


Figure 1. Model for improvement of chronic illness care (29)

Design

This study will include: **A)** a qualitative study of GP, practice nurse and patient views of acceptability and implementation requirements of the Patient Centred Assessment Method (PCAM); **B)** a feasibility study for a cluster randomised controlled trial to test the acceptability and feasibility of conducting a future effectiveness trial; **C)** A qualitative comparison of audio-recorded nurse consultations pre and during use of PCAM to assess fidelity of its use by nurses; **D)** A qualitative study of Nurse and patient perceptions of using PCAM in LTC annual reviews; and **E)** A qualitative process evaluation of the implementation of the PCAM and the trial implementation processes. The feasibility cluster RCT contains potential for 2 units of analysis, namely nurses as the unit of analysis (changes in nurse behaviour and consultation feedback on nurses behaviour) and patients as the unit of analysis (patient well-being and quality of life outcomes).

A) Acceptability and implementation requirements.

Six focus groups will be conducted in 4 practices, consisting of 4 professional groups (GPs and nurses) and 2 long term condition patient groups. Practices will be selected to reflect the same demographic mix as for the pilot trial participants but to avoid contamination (particularly of control practices) these will be a separate set of practices to the feasibility trial practices. The SPCRN will send out letters of invitation to practices in batches of 8 to practices on their register who meet the following criteria: medium to large size (4+ GP partners); based in NHS Greater Glasgow and Clyde (NHSGG&C), NHS Grampian, and NHS Forth Valley (NHSFV). We aim to recruit 2 from NHS GG&C, one from NHS Grampian and one from NHSFV. All GPs and practice nurses will be invited to participate (including GP trainees). It is anticipated that professional focus groups will likely be relatively smaller in size because of limited availability of time but will aim for 5-8 per group. The aim of the professional focus groups will be to determine any potential barriers to using the PCAM and how these might be minimised or overcome. Professional groups will discuss implementation of the PCAM within routine annual reviews. To facilitate the use of NPT as an analytic framework for understanding barriers and facilitators to adoption we will aim to identify whether and how nurses and GPs distinguish the PCAM from current ways of working; whether nurses and GPs collectively agree the purpose of the PCAM; how nurses and GPs individually understand what the PCAM requires of them; whether and how nurses and GPs construct potential value of the PCAM for their work; whether nurses and GPs agree that the PCAM is a legitimate part of their work; and whether and how they jointly intend to deliver the PCAM; Patient groups will discuss how wider aspects of their lives can impact on their health and how they would like to be supported to manage life difficulties; whether they feel primary care practitioners have a role in helping patients manage life difficulties that can impact on health. Patients will then be presented with the PCAM to discuss its utility and acceptability for use in their care, and how professionals might approach topics with patients. Patients will also discuss any potential barriers for patients that might impact on the nurse's ability to use the PCAM. Recruitment of patients will be via practice lists from one NHS GG&C practice and one NHS FV practice with letters of invite being sent to practice patients aged over 18 living with LTCs who require an annual review (mainly (Diabetes Mellitus (DM), Coronary Heart Disease (CHD), or Chronic Obstructive Pulmonary Disease (COPD)). SPCRN will extract and number these lists and sample patients based on multiples of 5 (number 5,10,15 on the list and so on). GPs will be asked to review sampled lists to exclude anyone who would have difficulty travelling to the practice or participating in a focus group (e.g. due to cognitive or communication impairment). Letters will be sent in batches of 10 and will require opt-in by the patient via text, phone or email to the researcher. Recruitment will continue until 12 patients per group have been recruited (to allow for a number of no-shows on the day). We anticipate 8-10 participants per group. Focus groups will be conducted on practice premises. All groups will be recorded and fully transcribed for analysis. Patient focus groups will include a mix of age and gender and reflect the general social demographic of the practice. The random nature of above sampling approach should result in the selection of a general spread of the practice population aged over 18 living with LTCs. However, if it is shown that those opting in to the focus groups are likely to yield a skewed sample (e.g. older adults or more affluent postcode regions) then the practice lists will be stratified by gender, age, and postcode region and SPCRN will sample as per above from the stratified lists.

B) Feasibility study of a cluster RCT of using the PCAM in primary care nurse assessments of patients with LTCs.

Sample size: As this is a feasibility study it is not appropriate to include a formal sample size calculation. We will be using a cluster RCT design, with GP practice as the unit of cluster, estimating pre and post implementation outcomes for 2 units of analysis, namely nurse and patient level outcomes.

One of the key outcomes for improving patient care is the change in nurse referrals/signposting to psychosocial supports. We require to understand the baseline of nurse behaviour in this regard in order to observe change in both intervention and control nurses. Nurse related 'outcomes' can only be measured post consultation (nurse referrals/signposting, CARE, PEI), whereas patient level changes in outcomes are likely to require some time (typically weeks) following the consultation before they can be observed. Therefore, changes in patient level outcomes (the GHQ, WEMWBS, SF12) cannot be measured by comparing pre and immediately post consultation scores. The design includes 8 week follow-up of patients to take account of the time likely required to observe change in patient level outcomes which may be influenced by actions resulting from the consultation (referral/signposting) rather than a direct impact of the consultation itself (e.g. empathy and enablement as measured by CARE and PEI).The 8 week outcome questionnaire will also ask patients about their up-take of any referral/signposting advice and reasons for non-up-take.

Recruitment of practices

Eight practices will be recruited from medium to large practices (4+ GP partners) in three health board areas of Scotland by the Scottish Primary Care Research Network (SPCRN) from their research register. Four practices will be recruited from the NHS Greater Glasgow and Clyde Glasgow 'Deep End' practices (most deprived practices in Scotland), and 4 will be from mixed affluence smaller city/town areas in NHS Grampian (2 practices) and NHS Forth Valley (2 practices) to represent the general spread of urban populations across Scotland.

"General Practitioners at the Deep End" work in 100 general practices serving the most socio-economically deprived populations in Scotland, based on the proportion of patients on the practice list with postcodes in the most deprived 15% of Scottish datazones. This ranking, based on the Scottish Index of Multiple Deprivation (SIMD), is published on the website of the Information Services Division of NHS Scotland. Membership of the Deep End, and rankings within the list, continually change as a result of periodic changes to SIMD, the disbandment and formation of practices, and patients leaving and joining practice lists. Homeless practices in Glasgow and Edinburgh have been co-opted to the group. Although practices may be added to the Deep End group, previous qualifiers are not excluded, as the population changes are usually small, with little change to the general situation in which practices work. The activities of the group are supported by: the Royal College of General Practitioners (Scotland); the Scottish Government Health Department; and General Practice and Primary Care at the University of Glasgow (a partner in this study).

The SPCRN will send out letters of invitation in batches of 8 to practices on their register who meet the following criteria: medium to large size (4+ GPs partners); from NHS GG&C Deep End cohort; NHS Grampian; NHS FV. They will exclude practices who took part in the focus group study. Each practice must also be able to recruit 2 nurses who deliver annual health checks for LTCs (Diabetes Mellitus (DM), Coronary Heart Disease (CHD), or Chronic Obstructive Pulmonary Disease (COPD).

Data collection:
Baseline data: Baseline data collection will be conducted prior to randomisation and will consist of immediate post consultation data collection for a cohort of 10 patients per nurse (n=160 patients) including: patient demographics, patient assessment of the consultation, patient completed outcome measures; and any Nurse referrals or signposting to services. From a given start date, all consecutive patients attending annual reviews by participating nurses will be asked if they would be willing to complete anonymised questionnaires following their consultation and at 8 weeks follow-up. All questionnaires relating to each patient, including nurse referral/signposting forms for each patient, will be linked using a unique code number for the study which includes a nurse and patient reference.

Practice staff will pre-prepare a patient addressed (pre-paid) envelope to be held at the practice and posted at 8 week follow-up. Patient completed questionnaires include the Care and Relational Empathy Measure (CARE), the Patient Enablement Instrument (PEI), the General Health Questionnaire (GHQ), the Warwick and Edinburgh Mental Wellbeing Scale (WEMWBS) and the Short Form-12 (SF-12). The 8 week outcome questionnaire will also ask patients about their up-take of any referral/signposting advice and reasons for non-up-take. Nurses will record demographic information on patients as well as any referrals or signposting undertaken at the review. This will be matched to patient questionnaire data using the unique study code number for the patient. SPCRN staff will use this unique code to identify non-responders and access their contact details for a reminder questionnaire. The research team will not have access to personal patient information.

The Depression Attitude Scale, will be used to measure changes in nurse attitudes towards depression. Equivalent scales are not available for other mental health problems; however, since depression is the most common mental health presentation in primary care, this is a good proxy measure of general attitudes and confidence regarding mental health. Additional bespoke questions regarding confidence in asking about mental health issues will also be included. Nurses will complete this at baseline prior to patient data collection and post intervention when patient data collection is complete.

The research team (project manager and research associate) will stagger practice start dates to ensure they are present during data collection at the first 2 clinics in each practice to address any problems and ensure the data collection process is running smoothly.

***Randomisation of practices to intervention or care as usual*.**
Following baseline data collection, practices will be randomly allocated to deliver the PCAM intervention (4 practices) and 4 allocated to deliver usual care (TAU). Practices will be randomly allocated to intervention or control by the SPCRN based on matched criteria as follows:

	Intervention	Control
Glasgow Deep End Practices	2	2
Mixed affluence/smaller city/town	2	2

PCAM Intervention:
The PCAM aims to provide a systematic language for the integrated assessment of a broad range of physical, mental well-being and social needs. It is also 'action oriented' so that if needs are identified – even if these extend the professional boundaries of providing physical health care- they will be acted upon at some level. This should improve overall patient experiences of the care they receive and lead to improved well-being in the longer term.

Intervention site nurses will receive a half day training in use of the PCAM and encouraged to use this with 10 patients prior to the implementation phase to gain confidence. Intervention sites will be supported by the project manager to assist with embedding PCAM into routine practice and support clinic participation in the research study.

In training, nurses will gain an understanding of the social determinants of health and how social factors can influence morbidity and mortality. They will also learn about the co-morbidity of physical and mental ill health building a picture of why it is important to conduct biopsychosocial assessment and address broader health needs. They will then be introduced to the PCAM and will discuss ways in which knowledge of the patient's circumstances can be elicited as part of a conversation (not a tick box exercise) and in a naturalistic way which builds on their communication skills.
The PCAM involves nurses making an assessment of their patient on the following domains:

- Health and Wellbeing (covering physical health needs; impact of physical health on mental health; lifestyle behaviors; mental wellbeing)
- Social Environment (covering home safety and stability; daily activities; social networks; financial resources)

- Health Literacy and Communication (covering understanding of symptoms, self care and healthy behaviour; how engaged patient is in discussions)

These then lead to action oriented tasks to deal with the identified problem which may include referral or signposting to other professionals or agencies. Nurses will be encouraged to think of the range of supports that are locally available. The research team will also work with the Access to Local Information to Support Self Management project (ALISS) to provide them with a list of potential referral/signposting opportunities which cover the biopsychosocial problems within the PCAM domains. The ALISS Engine acts as a central index for self management information in Scotland. It is used to collect, organise and share links to community support.

Care as usual:
Nurses in control practices will deliver care as usual to their patients which is normally guided by the requirements of the QOF for LTCs such as Diabetes and Coronary Heart Disease. The QOF requirement for screening for mental health problems in LTCs has now been removed but nurses may still include some attention to mental health and well-being in their assessment. Normal referral systems or pathways of care should be maintained.

Post intervention data collection: The same post consultation data will be collected for a second separate cohort of patients in both intervention and control practices (n=160 patients) following the introduction of the PCAM in intervention practices. The second cohort will also complete follow-up outcome measures at 8 weeks. We will also ask nurses to record instances whereby they identified patient needs that could not then be addressed by any existing and available services or where non-ideal services were advised or employed in place of more appropriate but unavailable services.

C) Fidelity of use of PCAM:
Five patients per nurse will be approached to consent to having their consultation audio recorded in both baseline and intervention phases to assess whether nurse practice has changed in any way since using the PCAM, and to validate how nurses use the PCAM. To avoid introduction of bias these patients will not be included in post consultation outcomes data collection. These patients will be recruited immediately following the post consultation data collection for each pre and intervention cohort and consist of the first five patients attending and consenting at the next LTC annual review clinic following quantitative data collection. Patients will receive a study information sheet on arriving at reception and will also have the request to audio-recording repeated by their nurse. The nurse will allocate their recording a number (identifying the nurse study number and a patient number) which will be given to the patient in case they want to withdraw consent later. Patients will then have up to one week to withdraw consent by texting, phoning or emailing the researcher as advised in the study information sheet.

D) Nurse and patient perceptions of using PCAM in LTC annual reviews:
Eight intervention nurses and 16 intervention patients will be asked to consent to a follow-up telephone interview. A request for interview will be sent to all study nurses and from those agreeing to interview the sample will be chosen to reflect the mix of study sites. Nurses will be asked about their perceptions of using the PCAM and whether they feel they have improved their interactions and assessment of patient needs, and particularly in relation to assessing mental well-being. In line with NPT, they will also be asked about barriers and facilitators to its useand whether nurses and GPs intend to continue supporting the PCAM. Interviews will also explore ‘enacting work’ associated with the PCAM: the tasks required to undertake the PCAM; whether the work involved in using the PCAM is allocated appropriately to nurses; and whether the PCAM is supported adequately within the practice. Finally, nurse interviews will explore ‘appraisal work’ in relation to the PCAM; do nurses collectively assess the PCAM as worthwhile work for patients; do nurses individually assess the PCAM as worthwhile work for themselves; and do nurses modify their work in response to their appraisal of the PCAM.

Patients of nurses who used the PCAM will receive a pre-paid postcard invitation to interview alongside their post consultation questionnaires. This can be filled in (personal contact details) and returned with their questionnaire or returned separately by post. A researcher will then contact the patient and further explain the purpose of the interview and arrange a suitable time. Interviews will be

conducted via telephone and digitally recorded. Verbal consent to the interview and the use of its data will be audio recorded at the start. Patients will be asked about: their consultation with the nurse and what general issues were discussed; their awareness of Nurses using the PCAM tool; whether they were aware of nurse attention to wider aspects of their well-being and what they thought of this;;whether they had received any health promotion/lifestyle advice or referral/signposting,and what they thought of this; and whether they acted on advice or referrals and reasons for action/non-action.

E) Process Evaluation:
A qualitative process evaluation will be used to identify possible contextual influences on the study implementation process across all study phases. This will also help identify potential barriers to running a future cluster RCT. Notes of meetings and discussions with staff and any comments to the research team or reported by practice staff from patients during implementation will be supplemented by the focus group data, planned interviews with staff and patients, and open ended questions on staff and patient questionnaires.

Data analysis
Quantitative outcomes: The primary outcome of the pilot trial is to determine recruitment and retention rates of practice nurses, and recruitment of patients and data completion for a future cluster RCT. We will also establish which nurse and patient level measures should constitute primary and secondary outcomes for a future cluster RCT, and determine sample size for a future trial. This current study combines data collection for two separate units of analysis: one with nurses as the unit of analysis and one with patients as the unit of analysis. One of the criteria for continuation would be to determine whether the number of nurses required for a cluster RCT is feasible and within reasonable cost boundaries. Such a design would be sufficiently powered at the patient level to again include 2 units of analysis – thereby testing the impact of the PCAM on both nurse behaviour and patient outcomes.

The characteristics of the nurse and patient groups, and estimable outcomes will be summarised by descriptive analyses, including formal significance tests where relevant, (expressed with effect sizes and estimates of precision). The PEI, CARE and signposting measures will be analysed at the nurse level; the GHQ, SF-12 and WEBWBS will be analysed at patient level; both units of analysis will be compared across groups and change in outcomes will be compared across intervention and control groups using a multiple regression framework with the follow-up scores as outcomes and baseline scores used as covariates in the model along with other time-fixed socio-demographic and clinical variables. Statistical software such as SPSS or Stata will be used throughout. All models will be adjusted for clustering within practices. Transformations of the outcome variables will be used where necessary, if they are not normally distributed. The choice of regression model will be determined by the type of outcome variable under scrutiny; for example, where the PEI score is used to determine 'enabling nurse score' versus 'non-enabling nurse score' a logistic regression model will be used. All analyses will be stratified by the stratification factors used in the randomisation process. Where data is collected on the same individuals at baseline and follow-up (for example the second patient cohort) the analyses will make efficient use of the 'dependent' nature of this data. The ICC will be estimated for all potential outcomes and the sample size estimates made for a future definitive trial. Wherever possible effect sizes will be presented together with estimates of precision and level of significance in accordance with stipulated CONSORT guidelines (www.consort-statement.org).The CSO NMAHP Research Unit will be responsible for data management, quality assurance and statistical assurance. The NMAHP Research Unit has substantial in-house expertise in conducting NMAHP trials and the statistician is supported by our senior statistician (Prof. Suzanne Hagen, Glasgow Caledonian University) and is also linked in to a network of NMAHP trial statisticians.

Qualitative analysis: the analysis is specifically intended to identify barriers and facilitators to adoption/use and will be informed by Normalisation Process Theory (15). NPT offers and explanation of the work of implementation, embedding and integration and specifically focusing on the contribution of individuals and groups as agents of change. NPT helps to explain how practices can become embedded in organisational and professional contexts. There are four generative mechanisms to help explain how change can become adopted and embedded: coherence (sense making), cognitive participation, collective action and reflexive monitoring. The production and re-production of a practice requires continuous investment by agents over time. NPT mechanisms are constrained (or aided) by the operation of norms (notions of how beliefs, behaviours, and actions should be accomplished); and conventions (how beliefs, behaviours, and actions are practically accomplished). The NPT generative

mechanisms and their constructs will form the framework for analysis of the qualitative data. NPT will be used to help understand and think through implementation problems and to help identify techniques to solve them. This will be made use of at the start of the project using the focus group data to help shape improvements to the implementation process and the training materials. Similarly the researcher fieldnotes and post-implementation interviews will be used to identify further barriers and facilitators to adoption which will be organised around the NPT generative mechanisms and their constructs. Qualitative data analysis of focus groups and interviews will be conducted using NVivo software. In an iterative process all focus group transcripts and a sample of interview transcripts will be reviewed by 3 team members (MM, CH,+ Research assistant) to identify key themes in relation to our research questions regarding acceptability, feasibility, impact on professional practice, and impact on confidence building in relation to mental health and in relation to the NPT generative mechanisms and constructs. These themes will be discussed and amended until a core set is agreed by all and will constitute a final coding frame which will be systematically applied to all data by the RA. Additional knowledge from researcher notes regarding implementation in sites will add to the focus group and post implementation interview data and constitute the (implementation) process analysis data. This will be analysed to identify barriers and facilitators to implementation and fidelity of use. Regular discussions will be held with this core team to share and confirm the findings of the analysis.

Analysis of audio-recorded consultations: This will consist of classifying conversation segments according to whether they attend to physical health, mental wellbeing or social elements of care. The PCAM should encourage a conversation flow that attends to wellbeing and social circumstances throughout the consultations (not left to the end when time may be limited). Analysis will therefore include attention to when conversation segments appear in the consultation. The range of social circumstances attended to will also be identified. Attending to a mix of physical, mental wellbeing and discussion of social circumstances through the consultation; and discussing a range of social circumstances will be considered as maintaining fidelity to the PCAM. It may be that nurses already know a patient's social circumstances well but they would still be expected to enquire about these – to ask how they are getting on, or any change in circumstances.

Analysis of key methodological issues for a future trial: combining quantitative and quantitative data:
Overall, the qualitative and quantitative analysis will attend to identifying whether and how a future cluster trial should proceed. This includes assessing whether recruitment, retention and data collection were achieved to a sufficient level, and whether the outcomes used are sensitive enough to detect change (at what level and for whom) as well as identifying any key methodological issues in converting from a feasibility or pilot to a full-scale trial as established by Shanyinde et al. We will use a tool for decision making after pilot and feasibility trials known as the ADePT process, which has been developed within the NMAHP Research Unit (publication submitted to Trials journal) based on a recent feasibility study and pilot trial for a randomised controlled trial (RCT) of pelvic floor muscle training for prolapse (ClinicalTrials.gov: NCT01136889). The ways in which researchers decide to respond to the results of feasibility work may have significant repercussions for both the *nature* and *degree* of tension between internal and external validity in a definitive trial.

The Adept process seeks to: 1) encourage the systematic identification and appraisal of problems and potential solutions; 2) improve the transparency of decision-making processes; and, 3) reveal the tensions that exist between pragmatic and explanatory choices.The ADePT process includes three stages: a decision about the type of problem, the identification of all solutions (whether addressed within the intervention, trial design or clinical context), and a systematic appraisal of these solutions. This will be applied to sample size, eligibility, recruitment, consent, randomization, adherence/fidelity of intervention, acceptability of intervention, selection of appropriate outcomes, retention and logistics of multi-centre sites, and whether all components of the protocol worked together.

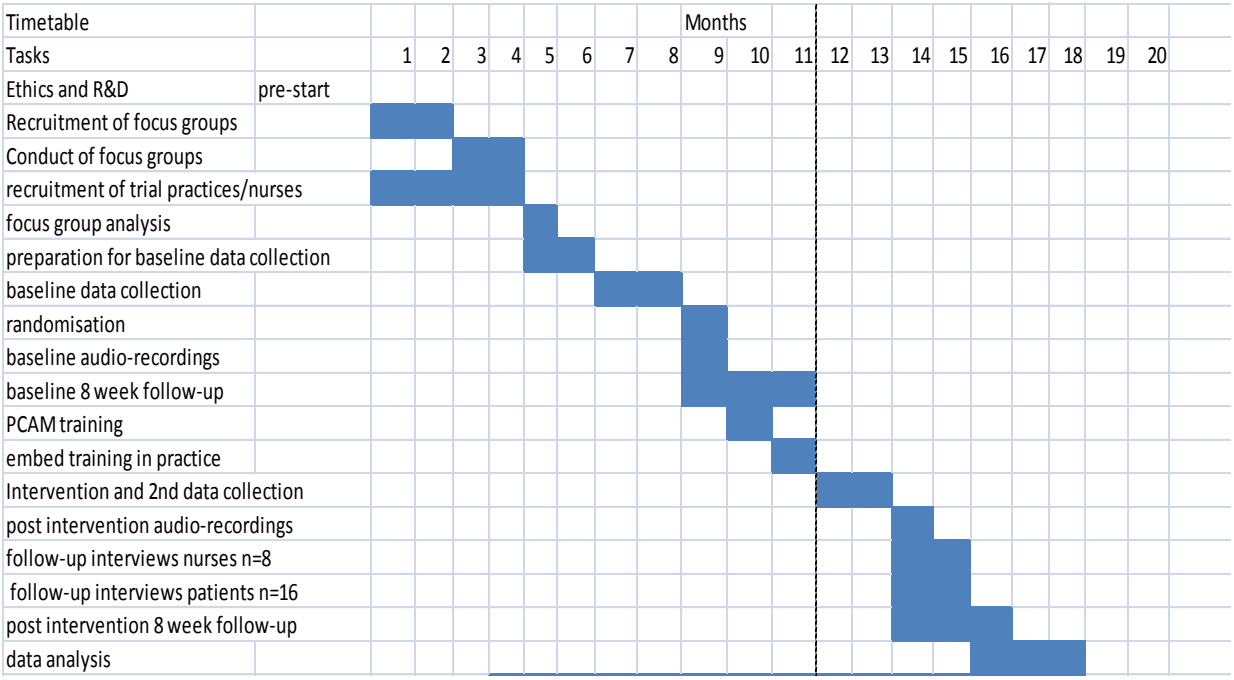
Dissemination and projected outputs

The PCAM and all associated materials, such as training materials and any best practice guides developed during the learning gained in this research, will be available for use freely via www.pcamonline.org. This website provides a central resource for the most current materials and information to be updated and made available. Currently we have partnerships where organizations are using or intending to use PCAM in a number of US states, Canada and Australia. While these

partners work in a range of settings, including primary care, mental health, HIV prevention, paediatric primary care and medical education, this is a foundational network of practitioners and academics through which we will disseminate findings and build further collaborations for learning.

Plan of investigation and timetable

Timetable: Ethics and R&D approvals will be sought prior to commencement of study and approximately 6 months have been allowed for this in calculating the start date. Recruitment to Focus groups months 1-2; Focus groups months 3-4; Recruitment of trial practices months 1-4; FG analysis and preparation for baseline data collection months 5-6; Baseline data collection months 7-8; Randomisation month 9; Baseline audio recordings month 9; Baseline 8 week follow-up months 9-11; Training of nurses month 10; Implementation of PCAM intervention and 2nd data collection months 11-13; Post intervention audio-recordings of nurse consultations months 14; Follow –up (24 interviews) months 14-15; Post intervention 8 week follow-up months 14-16;Process analysis: on-going from conduct of focus groups months 4-18; Data analysis months 16-18; Write up and commencing dissemination months 19-20.



Intellectual Property
The University of Stirling is a joint holder of the copyright on PCAM alongside the University of Minnesota. We are fully committed to ensuring the free and open distribution of PCAM and associated materials as part of our commitment to making a positive impact to patient care. The University of Stirling endorsed this arrangement when the contract for the Keep Well study was signed.

Other intellectual property arising from this project will be shared by the co-applicants.

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