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Improving nurse-led assessment of patients with long-term conditions and co-morbid mental health needs: a feasibility trial and process evaluation.

Short title: Patient Centred Assessment Method (PCAM): a feasibility trial

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Scientific Summary

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. 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 and contributed to little or no attention being paid in these assessments to the social problems that might contribute to poor physical and mental wellbeing. 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. The PCAM has previously been evaluated in anticipatory (Keep Well) health check clinics in Scotland but has not been evaluated for use by primary care Practice Nurses and its potential value for addressing mental wellbeing 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 aimed to assess the acceptability and implementation requirements of the PCAM for enhancing the care of patients with LTCs and co-morbid mental and social care needs in primary care. It also aimed to assess fidelity of its implementation/use amongst nurses (i.e. do they use it to explore the range of health and psychosocial domains covered by the PCAM), and to conduct a feasibility trial to determine whether a future full scale trial of its impact on nurse-delivered patient care and patient outcomes was feasible.

Methods: Practitioner and patient focus groups were used to assess the views of primary care professionals and people with LTCs about the acceptability and implementation requirements of the PCAM, especially for nurse consultations for LTCs. The PCAM was then tested in a

feasibility cluster randomised controlled trial which aimed to recruit eight GP practices and 16 Practice Nurses. Four practices (eight nurses) were to be allocated to deliver the PCAM intervention and four practices (eight nurses) would deliver care as usual. Baseline data collection was to be conducted in all practices with all study nurses prior to randomisation and consisted of immediate post consultation data being collected for a cohort of ten 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 would be collected by postal questionnaire at eight weeks follow-up. Practices would then be randomised to the PCAM intervention or to deliver care as usual. The same data would then 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 would also complete follow-up measures at eight weeks.

Fidelity of implementation and an understanding of how nurses used the PCAM, and whether it changed how they engage in assessments was tested via a sample of audio recorded nurse led annual assessments both pre (n=5) and during use of the PCAM (n=4). Follow-up interviews with nurses and patients were conducted to gain their reflections on the use and perceived impact of PCAM.

Outcomes: The primary outcome for this study was the comparison of recruitment and retention of nurses, and patient completion of questionnaires including follow-up completion rates with actual recruitment and completion rates. Patient outcomes tested for use in a future trial were the General Health Questionnaire-12 (GHQ-12), Short Form -12 (SF12) and the Warwick and Edinburgh Mental Well Being Scale (WEMWBS). Nurse behaviour was measured via: the number and types of referrals/signposting; patient evaluation of nurse consultations via the Consultation and Relational Empathy (CARE) measure and the Patient Enablement Instrument (PEI); and nurse confidence in dealing with mental health issues using the Depression Attitude Scale (DAS).

Qualitative focus group, interview and field-note data was used in a process evaluation to identify barriers and facilitators to the use and implementation of the PCAM, as well as the barriers and facilitators to conducting a future trial.

Results: From approaches to 159 eligible practices, fourteen practices expressed an interest in the study and six practices were recruited to take part in the study: five practices accepted the invitation to participate in both phases of the study and one to participate in Phase 1 only. Of the six participating practices, two had single Practice Nurses resulting in ten nurses overall. Following the completion of baseline recruitment, the five practices participating in both stages were randomised to the PCAM or Care As Usual (CAU) arms on a 2:1 ratio. This resulted in three practices (six nurses) being placed in the PCAM arm and two practices (three nurses) in the CAU arm for the second phase of research.
Nurse completion: Only seven out of the ten nurses (four practices) provided Phase 1 and Phase 2 data including nurse demographic and nurse outcome data. This would indicate that nurse retention is poor but when nurses are committed to participating data completion can be achieved.

Patient recruitment and completion: Each nurse was asked to recruit ten patients in each phase: This was achieved for by all nurses in Phase 1 (where 113 patients were recruited and completed questionnaires) and by six nurses in Phase 2 (where 77 patients were recruited and completed questionnaires). Only one nurse who participated in Phase 2 failed to recruit the ten patients required. This suggests that patient recruitment is achievable using the methods proposed in this feasibility trial. Patient follow-up in Phase 1 was approximately 60% and just under 50% in Phase 2. Reduced follow-up in Phase 2 was impacted by the delayed study timetable which did not allow for follow-up of all participants.

Fidelity of use of PCAM: Of the six nurses in the PCAM arm of the study, four agreed initially to have their consultations recorded, but, subsequently, only two nurses each recruited two patients pre- and post-PCAM. Of the remaining two nurses, only one recruited a single patient within the time given for this stage of the study, giving a total sample of nine patients (five pre- and four post-PCAM training). The analysis of recordings suggested that the PCAM does indeed change nurse behaviour in consultations. In pre-training consultations there was a strong focus on physical health and lifestyle behaviour domains and exploration of the impact of physical, lifestyle or other concerns on patients' mental wellbeing was not particularly evident. Post-PCAM training, there was more evidence of attention being given to the impact of physical, lifestyle or other concerns on patients' mental wellbeing with enquiry into these

areas beginning much earlier in the consultation. The use of the PCAM in consultations did not require any more time than usual.

Acceptability of PCAM intervention for nurses: For nurses the PCAM was fairly easily integrated into consultation, although some participants reflected that the process of integration took some time and support. Nurses reported that PCAM appears to help support a positive patient nurse relationship through increasing the quality and openness of communication, and the understanding of the patient's life. The nurse participants perceived this to be beneficial for both the patient and the nurse, both in relation to the quality of the relationship and the quality of the care provided. Nurses found the resource pack very useful and had been active in signposting patients to various supports. This seemed to be accompanied with an approach of helping patients to access support for themselves and to address what their own priorities were, rather than focusing on fixing purely clinical issues. Long term adoption of PCAM appears likely for some of the nurse participants in this research, beyond the research project itself.

Acceptability of PCAM intervention for patients: Patient participants interviewed did not notice any apparent difference to their annual review post PCAM implementation. However patients did describe talking with their nurse about their lives and their broader concerns during reviews and described welcoming these conversations with their nurse. PCAM implementation did not impact the consultation in any negative or obstructive manner. The use of PCAM to guide the consultation appeared to be seamlessly integrated into the consultation from the patient's point of view.

Process evaluation: There needs to be flexibility in how training and supported is delivered. Brief training followed by nurse reflection on PCAM with testing small areas of the PCAM and building up to using a full PCAM can be interspersed with training/support sessions as nurses become more familiar and confident with the process or need to come back and ask questions. Training needs to include more on boundaries and how to deal with complex issues over a number on reviews. There is a need to further emphasise where PCAM fits into the 'Pyramid of Psychological Need'. When this was emphasised in later training sessions, it helped the PNs see that it was not designed to solve all problems.

The Resource Pack is an integral part of the PCAM intervention for ensuring nurses feel confident that they can do something about issues raised during consultations. Practices need to identify a Resource champion who can keep the resource list up to date. In some cases the practice manager saw this as a role they could fulfil.

Overall, there were few adaptations required to the PCAM intervention beyond flexibility in delivery of training.

In relation to trial implementation, further work would be needed to establish whether recruitment efforts focused on Practice Nurses would yield better practice participation as well as other incentive schemes such as back-fill of nurses' posts for study duration. Dedicated researcher support is needed to support data collection in both phases, especially for the first couple of clinics or until researchers are confident research processes are operating as required.

More exploratory work is needed into acceptable methods for monitoring adherence/fidelity to the PCAM by nurses and understanding nurse reluctance to consultation recording.

Conclusions: The PCAM has been shown to be feasible and acceptable for use in primary care in the UK and shows that it does indeed have potential to change the ways in which nurses engage with patients with long term conditions in the context of LTC reviews which results in more attention to mental wellbeing and social care needs of patients. PCAM is more likely to be feasible when nurses: see the asking of these questions as part of the role of nursing; they view their role as facilitating links to information or resources that can address concerns (rather than feeling they have to address the concerns themselves); they have the information about resources available to them; and there is a whole practice commitment to the approach. Any future study of implementing or testing the PCAM in primary care would require these conditions to be met.

A cluster randomised controlled trial would be theoretically possible at a practice site level; however, given the above conditions this would be resource intensive and may require a different approach to working with practices to establish their 'state of readiness' (such as an improvement methodology) and a different research design to evaluate adoption and impact.

Additionally, the efforts required to recruit to a primary care based cluster randomised trial and the current 'crisis' climate of primary care (which seems to prevent many practices from engaging with research even when 'interested') would further indicate that a full cluster trial is not feasible or in any way cost effective at this time.

Recommendations: The PCAM intervention warrants further exploration as an effective mechanism for improving the quality of care for people with LTCs in primary care, particularly in the holistic review of patient needs by primary care nurses.

A full-scale cluster randomised trial is not recommended within the current climate of primary care research participation in Scotland. This may also include the rest of UK general practice and a brief survey by Primary Care Research Networks in England may determine whether this is also the case in England.

Research should explore nurse reluctance to having their consultations recorded to assess whether this is still a potential mechanism for assessing fidelity to the PCAM.

Alternative acceptable methods to exploring fidelity to the PCAM should also be explored. This may include observational methods by peers.