Interventions to improve adherence to medication in people with type 2 diabetes mellitus: the role of nurses

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Summary

Nurses now provide the majority of education and support for people with diabetes both in community and hospital settings. However, there are very few studies on nurse-led interventions to improve adherence to medication, a crucial element of the self-management of diabetes.

The four studies reviewed formed a subgroup of a Cochrane review on interventions to improve adherence to medication in people with type 2 diabetes. Search terms were 'type 2 diabetes mellitus' and 'compliance' or 'adherence'. Studies were included if they assessed adherence to medical treatment specifically, rather than other aspects of self-management. Out of the 21 studies selected for review, four described an intervention delivered by a nurse.

All four studies were from the USA and used an intervention delivered by telephone. Different interventions (two educational programmes, one automated telephone management system, one tracking system for health service and medication use) were backed up by a scripted nurse call. While patients in two studies reported improvements in self-care behaviour, only one measured a significant improvement in blood glucose control. Although some studies asked patients to report on their adherence to medication taking, responses from patients were not explicitly presented.

The studies reviewed show the potential for generating evidence for the effectiveness of nurse-led diabetes management programmes. Further high-quality studies into this area are desperately needed, and they should consider new ways of evaluating complex interventions to generate more evidence.

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Key words

Type 2 diabetes mellitus; diabetes specialist nurses; adherence; patient education; complex interventions

Introduction and background

Diabetes mellitus is one of the most common chronic diseases. The number of people with type 2 diabetes mellitus is continuously increasing worldwide. There are estimated to be more than 194 million people with diabetes worldwide, and half of them have not yet been diagnosed.[1] Once diabetes has been diagnosed, lifestyle adaptation is indispensable, and treatment with hypoglycaemic medication is common in order to delay or prevent more serious diabetes-related complications. Adherence to medication has been acknowledged to be a major healthcare problem involving both consumers and healthcare providers, as less than half of patients adhere to treatment or healthcare recommendations as proposed.[2]

The management of diabetes is a complex, lifelong process requiring a great deal of effort on the part of the person living with diabetes. They, more than any healthcare providers, are the key to successful management. Poor management can result in a number of serious complications. For this reason, non-adherence with therapeutic regimens among diabetes patients has been a continuing problem for healthcare providers.[2,3] A recent systematic review of adherence to medication for diabetes found that many patients were poor compliers with oral hypoglycaemic treatment; adherence ranged from 67 to 85% of doses.[4]

In many countries, diabetes specialist nurses provide the majority of patient education and support in both community and hospital settings.[5] In the US, for example, this role used to be filled by clinical case managers; diabetes nurse educators

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with an additional qualification allowing them to manage diabetes care. In working closely with individual patients to integrate lifestyle and medication issues, they have been described as crucial for the success of diabetes clinics or programmes.[6] In Europe, the UK National Health Service is developing a variety of new diabetes nursing roles in order to improve continuity of care.[7] The Diabetes Nursing Association in Turkey has instigated specialist training for nurses.[8] Similar role developments are happening in Italy[9] and Slovenia.[10] Interventions carried out by diabetes specialist nurses have been found to improve patient outcomes in randomised controlled trials.[11,12] However, others have argued that, while diabetes specialist nurse interventions improved patient satisfaction, their impact on metabolic outcomes has not yet been established, at least not in the long term.[5,13]

Clearly, studies of nurse interventions to improve adherence to medication for diabetes are crucially important. This paper reports on nursing interventions that formed a subgroup of a Cochrane review of 21 studies reporting interventions to improve adherence to medication taking for patients with type 2 diabetes.[14] The review included randomised controlled trials (RCTs), controlled studies, controlled before and after studies, and observational or prospective cohort studies. Although many studies of nurse interventions to encourage lifestyle change in areas like diet or exercise were found, almost none included or measured adherence to medication. Only eight studies, from the US, Canada and Sweden, were selected initially, four[15–18] of which were later excluded because they did not aim at improving adherence to medication. The remaining four[19–22] were examined in detail. All were from the US and reported only quantitative data.

Studies reviewed

All four studies reviewed used a telemedicine approach using the telephone. Different interventions (educational programme, automated telephone management, tracking of service and medication use) were backed up by a scripted nurse call aimed at formulating healthcare goals and reinforcing behaviour change. Adherence to medication was part of the adherence behaviour addressed in the nurse calls.

A comparison of the effectiveness of education classes plus weekly nurse telemedicine 'home visits' versus usual care for veterans with type 2 diabetes[22] showed a statistically significant reduction in mean glycated haemoglobin level (from 9.5% to 8.2%) in the intervention group over 3 months. The mean weight reduction was limited to a non-significant 4%. There were no significant changes on the Diabetes Quality of Life or the Medical Outcome Health Survey scales (SF-36). Metabolic parameters (microalbuminuria, serum creatinine and serum lipids) did not improve during the study period. Reinforcement of correct medicine taking was part of the nurse call script, but not measured as an outcome of the study. The study was randomised and controlled, but the participant groups were very small (intervention 15, control 13), and the randomisation process was not clearly described. Thus, education and telephone support seemed to improve glycated haemoglobin but none of the other outcomes measured. The effect on medication taking is not known.

Nurse researchers from the University of Alabama School of Nursing conducted a structured telephone follow-up to an educational programme for hospitalised elderly patients with diabetes, assessing self-care knowledge and behaviour and giving counselling/instructions on self-care.[21] They used a self-report checklist to discern deviations from the prescribed self-care programme which were used to calculate a behavioural deficit score. While significant improvements were found in the areas of blood glucose monitoring, diet adherence and symptom report, the only aspect of medication administration that showed a significant change was prevention of hypoglycaemia. Results for knowledge of dosage, hypoglycaemia recognition and treatment were non-significant. Adherence to medication was only applied to insulin, and the participant groups were again very small (intervention 15, control 12). In this study, medication adherence was targeted and reported, but there were no explicit reports of changes in taking medication.

A nurse-led automated telephone management intervention, with weekly follow-up nurse calls to talk about self-care, medication adherence and symptoms[20] showed a small but statistically significant ($p=0.04$) lowering of glycated haemoglobin for patients with an initial level of ≥8. Patients in the intervention group also reported more frequent glucose self-monitoring and foot inspections and a 10% reduction in diabetes-related symptoms. However, there was no significant lowering of glycated haemoglobin levels for the entire intervention group. Randomising and control processes were clearly described, and participant groups were sufficiently large (intervention 132, control 140). Although adherence to medication was targeted, the outcome measure was glycated haemoglobin, so we cannot be sure whether medication adherence improved.

Another nurse call programme conducted by a private US healthcare provider (American Healthways) focused on improving participants' understanding of their disease and the crucial importance of adhering to

Author	Intervention	Follow-up (months)		n	Age	HbA_{1c} (start)	HbA_{1c} (end)	p in groups	p between groups
Clarke[19]	Nurse-delivered commercial diabetes management programme and telephone follow-up	n/a	INT.	♂= 362 ♀= 386	mean 59	n/a, looked at service use	n/a, looked at service use	<0.001 for service use	n/a
Piette[20]	Automated telephone disease management	12	INT.	♂= 126 ♀= 6	60 ± 10	8.2 ± 1.7	8.1 ± 0.1	?	n/s
			CON.	♂= 138 ♀= 1	61 ± 10	8.1 ± 1.7	8.2 ± 0.1	?	
Tu[21]	Education programme and telephone follow-up	3	INT.	♂= 5 ♀= 10	65.6 ± 7.0	?	11.76 ± 3.1	?	n/s
			CON.	♂= 4 ♀= 8	65.25 ± 6.0	?	11.33 ± 1.67	?	
Whitlock[22]	Education classes and weekly telemedicine visits	3	INT.	♂= 6 ♀= 9	61.5 (41–73)	9.5 (8.1-12.6)	8.2 (5.7-10.2)	<0.05	?
			CON.	♂= 5 ♀= 8	59 (32–75)	9.5 (8.1-11.9)	8.6 (7.1-11.9)	n/s	

n/a: not applicable; n/s: not significant.

Table 1. Summary of results from reviewed papers describing interventions to improve adherence to medication in type 2 diabetes

standards of care while providing support in helping patients to change their behaviour and lifestyle.[19] A survey of 748 Diabetes Healthways[SM] programme participants focused on self-reported adherence and utilisation of medical services. However, this sample was not compared to usual care in public health settings. There were no differences in scores for medicine taking, taking medical tests or use of preventive health services. Patients in the intervention group had more frequent tests for glycated haemoglobin, low density lipoproteins, microalbuminuria and retinopathy. Thus, there was no beneficial effect on medication taking.

Discussion

The studies reviewed indicate that there is a lack of evidence on the effectiveness of any nurse-led intervention to improve adherence to medication taking in type 2 diabetes. It is possible that, since nurses are not traditionally seen as related to the prescribing and management of medication, few studies of nurse interventions even include adherence to medication as an outcome measure, and where they do, it is as a small part of more general 'lifestyle' interventions. It has been argued that adherence is a dysfunctional concept in diabetes care that should be replaced by collaboration between patient and health professional.[23] However, diabetes specialist nurses are familiar with the patients' individual circumstances and would have opportunities to discuss the integration of medication taking with everyday life as part of an empowering approach.

One important issue that arose from the review is the complexity of the diabetes nurse's role that makes it difficult to design the randomised controlled studies favoured by systematic reviews. Even though nurse calls were scripted, the personalised feedback and education gave considerable scope to individual nurses' skills in listening to and educating patients. Researchers designing RCTs of complex interventions must take on board recent debates about how best to do this. On the one hand, better design can avoid possible bias due to inappropriate blinding processes.[24] On the other hand, it is important not to transfer the strictures of simple interventions with tightly controlled components to complex interventions where the function and process of the intervention should be standardised, not the components themselves.[25]

In the UK, the Medical Research Council has developed a framework for research on complex

interventions: a process of exploring and testing the 'active' components of an intervention in order to decide which components should be constant and which variable.[26] Researchers at Warwick Diabetes Care concluded that the Medical Research Council Framework for complex interventions enables the researcher to describe and demonstrate the relevance of early nursing studies to the long-term development of nursing interventions.[27] Another possible avenue for researchers is a qualitative approach focusing on the gains to be made by nurse involvement in care. The reviewers would have preferred well-designed qualitative studies over those with a controlled design but there were too few participants to make their outcome data meaningful. Researchers could also adopt a mixed method approach to capture complex aspects of the intervention that fall outside the confines of the RCT design.[24]

The second point is that the greatest difficulty with interventions aimed at enhancing adherence to medication lies in actually measuring it. Adherence is complex, can vary over time and is bound up with the need for integration with social life as well as health beliefs.[28–30] People with diabetes can be non-adherent out of forgetfulness or because the medication regimen is too complex to fit in with daily life, but also because of worries about weight gain, or side-effects.[4,31] They may also reduce medication doses or omit medications to reduce the co-payment they have to make. Although this is a recognised problem, especially in the United States,[32] none of the articles reviewed addressed this issue. Non-adherence can be either intentional or unintentional. In spite of this complexity, single, easy-to-measure outcome variables are often used to indicate adherence, e.g. Whitlock's claim that body weight is a good indicator of overall adherence.[22]

The studies reviewed illustrate this point. Three of the four studies reviewed (Tu, Piette and Whitlock) used glycated haemoglobin as the main outcome measure, but only one (Whitlock) found a statistically significant reduction in the intervention group. Whitlock used the Diabetes Related Quality of Life and the SF-36 scale, but did not report results other than 'no significant changes'. Tu, Piette and Clarke included patient reports on diabetes self-care and service use. In Tu's study, the researchers themselves monitored patients' self-care behaviour, so that there could be pressure to give the 'right' answers; the same could be said about Clarke, where a market survey organisation asked the questions. In both these studies, self-care behaviour was measured against a generalised, prescribed self-care programme, whereas more recent diabetes self-care interventions have stressed an individualised approach aiming at goal setting and self-efficacy.[33,34]

The use of blood glucose control as an indicator of overall adherence can lead to 'black box' research: conducting an intervention and measuring glycated haemoglobin at the end of the study period, without exploring which aspects of the intervention made metabolic parameters change or remain unchanged. On the other hand, complex and ever-changing elements of self-care behaviour are very hard to measure. Since adherence is multifactorial, studies aiming to measure adherence might concentrate on clearly defined single aspects of adherence, with relevant, tailored outcome measures.[30] In the case of adherence to medication, this could include process measures like patient diaries/logs, 'intelligent' medication containers recording openings (e.g. MEMS), and qualitative explorations of obstacles to medicine taking and the experience of day-to-day self-care. Scales measuring self-efficacy and health-related quality of life could also provide a meaningful context to outcome measures.

Implications for further research

Although numbers of participants were small in two of the studies (Tu and Whitlock) and outcome reporting tended to be patchy, this review shows the potential for generating evidence for the effectiveness of nurse-led diabetes management programmes. Further studies into this area, which should consider new ways of evaluating complex interventions to generate more evidence, are desperately needed. Studies should also clearly define what they mean by adherence to treatment, and include outcome measures that address the multifactorial nature of adherence. There is also a need for qualitative studies exploring the impact of these interventions on patients and nurses. For example, if a prescribed dose of oral hypoglycaemic agents is not taken by the patient – medication non-adherence – it is often likely to be ineffective. If a dose of a medication is ineffective in diabetes care, then the prescription dose is increased and/or the drug changed. Clearly, such stepped changes in prescriptions may be based on misinterpretations of the evidence. We need to know that the medication has been taken before we can assess its effectiveness. Thus, interventions targeted at improving adherence, and which have been shown to be effective, are urgently needed. The interventions probably already exist and are being used by nurses, but this systematic review of the published research evidence, reported here, demonstrates the dearth of evidence on those interventions. This is an opportunity which should be seized for a research programme in diabetes nursing.

Conflict of interest:
None

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