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Title: A nurse-led interdisciplinary approach to promote self-management of type 2 diabetes: A process evaluation of post intervention experiences.

Running Title: A process evaluation of a nurse-led intervention

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Abstract

Rationale, aims and objectives: Self-management of type 2 diabetes through diet, exercise, and for many medication, are vital in achieving and maintaining glycaemic control in type 2 diabetes. A number of interventions have been designed to improve self-management but the outcomes of these are rarely explored from a qualitative angle and even fewer through a process evaluation.

Method: A process evaluation was conducted using a qualitative design with participants randomized to an intervention. Seventy three people living with type 2 diabetes and hyperglycaemia for a minimum of one year, randomized to one of two interventions (n=34 to an education intervention and n=39 to an education and acceptance and commitment therapy (ACT) intervention) completed stage one of the process evaluation, immediately following the intervention through written feedback guided by open-ended questions. A purposive sample of 27 participants completed semi-structured interviews at 3 months and 6 months post-intervention. Interview data were transcribed and data analysed using a thematic analysis.

Results: The majority of participants described an increase in knowledge around diabetes self-management and an increased sense of personal responsibility. Participants also described changes in self-management activities and reflected on the challenges in instigating and maintaining change to improve diabetes management.

Conclusion: The complexities of implementing change in daily life to improve glycaemic control indicates the need for ongoing support post-intervention which may increase and maintain the effectiveness of the intervention.

Introduction

Glycaemic control is the primary goal in diabetes management and the key factor in the development of long-term complications (1). Living with diabetes presents many challenges, including daily choices and actions that have a direct impact on blood glucose (e.g. exercise, stress, and for many, medication management) (2). The short and long term effects of hyperglycaemia are multiple, including microvascular (e.g. retinopathy, nephropathy, and neuropathy) and macrovascular (e.g. heart disease) changes.

Interventions to improve glycaemic control can be broadly categorised into educational interventions and behavioural interventions. Focused educational interventions have generated inconsistent results with some studies focusing on diet or exercise alone leading to a positive effect on measures of diabetic control (3). Group-based, diabetes self-management education programmes for people with type 2 diabetes have demonstrated improvements in health outcomes including improved glycaemic control and increased diabetes knowledge, self-management skills and self-efficacy/empowerment at six months (4), however, an understanding of the effective components of interventions have not been generated. Group-administered psychotherapeutic interventions have described therapeutic effects related to the nature of groups (5) and caution that factors directly related to the group dynamic, rather than the “intervention” can influence outcomes (6).

Qualitative evaluations of interventions are rarely reported but offer opportunity for the development and evaluation of complex and other health interventions, including the intervention process, and the feasibility and acceptability of the intervention, to improve and adapt interventions (7, 8). Qualitative research post-intervention can provide valuable insight into the study outcomes generated by quantitative measures (9). Although the need for

methodological research on the use of qualitative approaches in randomised controlled trials has been widely discussed (10), a review of 100 trials (7) found that whilst associated qualitative work had been conducted in relation to 30 of the trials, only 19 of these were published. In addition, the majority (n=14) were completed before the trial (nine during the trial, and four after the trial). The paucity of qualitative studies to explore trial results was further underlined in a systematic review of 296 publications (11) that reported qualitative findings alongside trial results. Only 1% (n=5) of the qualitative research related to the trial outcomes.

The aim of the process evaluation was to explore the acceptability of the intervention and gain insight into people's experiences of implementing the intervention in to everyday life up to 6 months post intervention.

Methods

Participants were randomized to either an education intervention an education plus Acceptance and Commitment Therapy (ACT) intervention or usual care. Participants in the usual care group were advised to continue with their care as normal and for many this will include visits to their general practitioner and practice nurse, although the frequency of these visits will be variable. The national guidelines support at a minimum an annual diabetes check (12). Both of the intervention workshops consisted of a one day workshop held at a central city location. The workshop ran from 10am to 5.30pm with a one hour lunch break. The interventions were developed by the research team, primary care nurses and an advisory group. The main content was based on the topic areas deemed to be important cross three established international diabetes education programmes (13, 14, 15). The research team included experienced educators and clinicians who developed a format for delivery that

promoted engagement in learning and discussion and included visual learning and active exercises, such food labelling. The interventions were developed into work books for the participants and a powerpoint slide presentation for the presenters. The package was reviewed by the advisory group, who included a consumer, clinicians and Maori and Pacific Island advisors. Both interventions were piloted with a small group of volunteers who were diagnosed with type 2 diabetes but who had experienced hyperglycaemia for just under one year and so did not fully meet the study criteria. Feedback on the content and delivery from the participants and the nurses were incorporated. Changes were minimal and related to using one diagram over another for example rather than changes to the topics covered.

The education intervention

The education intervention sessions were run by two primary healthcare based nurses who were trained in the delivery of the intervention by two of the study investigators. The education intervention covered the topics of the basic pathophysiology of diabetes, understanding diabetes and glucose, understanding the risk factors and complications associated with diabetes, food groups, portion sizes, self-management of diabetes through, diet, exercise, medication, and stress management, monitoring diabetes, including awareness of hypo and hyperglycaemia, and when to seek help. Underpinning the content were the themes of increasing understanding, how to take control and planning for the future. The intended changes related to increasing understanding of diabetes, satisfaction with diabetes management, an increase in self-management activities and maintenance or improvement of mental health, as measured through anxiety and depression.

The education plus ACT intervention

In the education plus ACT intervention, time was divided equally between the education intervention and the ACT intervention. Participants received the same content in terms of education but did not have the opportunity to discuss the material in as much depth as the education only group nor spend as much time on self-directed exercises in the handbook during the workshop. The ACT component addressed mindfulness and acceptance training in relation to difficult thoughts and feelings about diabetes, exploration of personal values related to diabetes, and a focus on the ability to act in a valued direction while contacting difficult experiences. The ACT component drew on material developed in a previous study (14). The workshop was led by a mental health nurse with expertise in ACT who received supervision from a clinical psychologist. The education component was delivered by one of the nurses providing the education intervention.

The intended changes related to increased acceptance of diabetes-related thoughts and feelings and a reduction in the extent to which thoughts and feelings interfere with valued action, increase in understanding of diabetes, satisfaction with diabetes management, an increase in self-management activities and maintenance or improvement of mental health, as measured through anxiety and depression.

Inclusion criteria for the wider trial were: aged 18 years or over with a confirmed diagnosis of type 2 diabetes and HbA1c outside of the recommended range (4-7%, 20-53 mmol/mol) for 12 months or more. Persistent, suboptimal glycaemic control was defined as having at least two records of HbA1c > 7%, 53mmol/mol, in the past 12-18 months, including HbA1c >7%, 53mmol/mol on recruitment. Exclusion criteria were non-English speaking, pregnancy, short-term or serious medical conditions, currently in psychotherapy or participation in a diabetes education programme in the past 12 months. The intervention took place in a

community based location in a city in New Zealand. The primary outcome of our study identified that those who received the education-alone intervention demonstrated a statistically significant improvement in glycaemic control at 6 months ($p=0.01$). Glycaemic control in the usual care group deteriorated at six months and some improvement in glycaemic control was noted in the education plus ACT group at six months although this did not reach statistical significance. Participants in the intervention groups provided data on their perspectives of the process of the delivery of the intervention and a subsample ($n=27$) provided follow-up data on the outcomes of the intervention.

For the qualitative evaluation, all those who completed the intervention ($n=73$) were invited immediately following the intervention to provide written feedback on the intervention. A sub-sample of participants ($n=27$) selected purposively by gender, age and time since diagnosis (≤ 5 years, 6-9 years, ≥ 10 years) to ensure representation across the three variables, were invited to complete a semi-structured interview at 3 and 6 months post intervention, the same data points for which quantitative data were collected.

At baseline, data were collected through written responses to open ended questions and at 3 and 6 months through semi-structured interviews. At baseline, the open ended questions related to the areas participants felt were the most valuable, least valuable and any areas that were not covered in the intervention. Participants were also asked about completing the intervention in a group setting and to add any further comments and suggestions. At 3 and 6 months post intervention, semi-structured interviews were completed by one author (VM) either by phone or in person (based on participants' preference). The interviews were digitally recorded and then transcribed verbatim. The interview questions directly related to

what participants felt they had gained (or not) from the interventions, the impact of this on diabetes management and any issues that may have impacted on diabetes management.

The process of thematic analysis (TA) has been described by Braun and Clarke (16) as a theoretically flexible method that organizes, describes and interprets qualitative data. The first step in the TA involved becoming closely familiar with the data by reading and re-reading the interview transcripts. Following this close reading, initial codes were generated. This involved examining the data keeping the research aim at the forefront. One author (LW) conducted the close reading of the transcripts, generated the codes and clustered these into categories. These categories were then integrated into themes following discussion with the research team members. Once the themes were identified they were named, defined and described. This was followed by a process of illustrating each theme with relevant excerpts from the transcripts. A process of thematic verification involved another author (MC) examining the audit trail of codes, categories and themes in relation to the transcribed interview. The final phase was a synthesis of themes. This involved exploring the relationship of the themes to each other and to the socio-cultural context within which they emerged (17). It is at this point that the presentation of that the process shifted from a descriptive process to an interpretive process to identify meanings embedded across the data and what Braun and Clarke (16) describe as making an argument in relation to the research question.

Results

Twenty seven people were interviewed, with a balance by gender (female n=13, male n=14), age (43 years to 65 years, average age 55 years), and by time since diagnosis (n=8 ≤5 years, n=8 6-9 years, n=11 ≥10 years).

One core theme and three sub-themes emerged from the analyses. The core theme, “managing diabetes is vital, but challenging”, described the participants’ over-arching response to the interventions. The sub-theme, “increase in knowledge”, described change in knowledge in relation to specific areas of diabetes self-management. The sub-theme, “increased sense of personal responsibility”, described changes in participants’ understanding of their role in managing diabetes. The third sub-theme, “changes in self-management activities” related to changes and challenges in instigating and maintaining change to improve diabetes management.

Managing diabetes is vital, but challenging

All participants described a recognition that active management of diabetes is vital to health and well-being. All participants acknowledged that they had a role to play in managing their health through self-management but described making changes and sustaining these over time as challenging. The core findings were directly related to the intervention and the subthemes illustrate how participants reached these positions through the intervention in relation to an increase in knowledge and awareness of personal responsibility, which, in turn, impacted on the management of diabetes and outcomes.

Increase in knowledge

Immediately following the intervention, two thirds of participants described an increase in knowledge in relation to specific areas of diabetes management as the most valuable aspect of the intervention. The nature of the knowledge described immediately following the intervention was synthesised into knowledge related to diabetes as a disease, the consequences of diabetes and the management of diabetes:

Even though I've had diabetes for many years I learnt a great deal about what exactly diabetes is. EDACT56

Understanding diabetes and the consequences if you don't do anything about your diabetes. ED 92

In the follow-up interviews, the majority of participants (n=21) described learning a substantial amount, with a major increase in knowledge:

Oh it gave me a bigger understanding well I understood an awful lot more than I did before, although I went to a diabetic session at the hospital I came out and I still didn't know some of the things. ED166

I really understood after the workshops before it was really just a hit and miss type of situation all the time. EDACT112

Six participants described a mix of learning new information and refreshing knowledge in other areas.

In relation to the education workshop (both groups), the areas participants described as most useful were an introduction to the pathophysiology of diabetes (n=2), understanding the pharmacodynamics of the medications they were taking (n=8), recognising the warning signs of hypoglycaemia and how to manage this (n=2), dietary advice (n=9), understanding the benefits of exercise in relation to glycaemic control (n=2) and the long term effects of diabetes and the importance of check-ups (n=6):

I didn't realise, what is it, the beta cells in your pancreas because of the ongoing high sugar levels actually get killed off and you can never recreate those. EDACT171

I basically didn't know that the pill I take (Glipizide) opens up, she said to take it half an hour before your meal, well I was told to take it at meal times. EDACT174

I understand a lot more about why I was testing because I didn't understand it before exactly why I was testing, you know what affects me, what food affects me ED166

I think the business about the, you know, how the three month testing works, because I couldn't see how you could take a blood test on one day and know what had happened over the next three months EDACT126.

If you don't do your exercise, well it just, I was going to say makes the diabetes worse, you know, you struggle with your blood sugars more. EDACT147

I learnt a lot about your feet and foot care and pins and needles and things like that ED195.

There were no differences in the proportion of participants in each intervention group who demonstrated an improvement in glycaemic control by type of change described (e.g. change in medication management or diet) by intervention group.

Increased sense of personal responsibility

The sub theme, increased sense of personal responsibility, encompassed the changes participant's described in understanding their role in managing diabetes following the intervention. Directly following the intervention, one third of participants described the most valuable aspects of the intervention as related to an increased understanding of their own role and responsibilities in managing diabetes:

to now understand what I can do to control my condition EDACT142.

Two thirds of participants responded that they felt they now had an increased awareness and ability to self-manage as a result of attending the intervention sessions and one described the inter-relationship between self-management and an increase in knowledge base:

It's given us enough knowledge to help ourselves EDACT142

I learnt lots and now I have to put it to use EDACT56

Two thirds of participants who described an increased awareness of the importance of self-management and an increase in the ability to self-manage following the intervention described this as a refocusing on diabetes:

To be reminded that it is all up to me. A chance to refocus on my diabetes EDACT71

Being encouraged to think about my diabetes, rather than push it aside EDACT127

In the interview data at 3 and 6 months post intervention, five people described a significant change in their outlook on diabetes and their health, a "Wake up call" (EDACT171) as a direct result of the intervention.

At the follow-up interviews, nine participants described developing an increased sense of confidence in relation to managing diabetes that allowed them to take greater control of the management process. Participants described an ability to interact with their primary health care provider in a more confident and knowledgeable way:

I probably learnt quite a lot about the medications you know like I didn't know what the medications were, what Glipizide did and of course the doctor was quite surprised when I told him what it actually did and he said oh how did you know that I said oh I read a lot of books no actually I've been going on a course so I explained what was going on and he said oh that's good and he's actually got your results too.

EDACT210

The increased sense of confidence led nine participants to actively address what they now saw as deficits in their care. Participants either discussed these with their primary care provider (n=7), or changed their primary care provider (n=2):

It was made quite clear that you know the seminar wasn't a checklist for what your doctor should be doing but you know like there's quite a lot of stuff that I had never heard of that was brought to my attention then so yeah I've sort of come to terms that I was with my first doctor who sort of hadn't done a great deal about it so I'm sort of hoping that my new doctor will do more, yeah. ED106

Well it got about really through the education programme that initially after I went to the education day next time I spoke to my doctor I talked about it oh you know how I'd

been advised on that to actually get a blood monitor and with my previous readings I should really be on medication. And he basically his attitude was well you're in a busy job you probably don't have time to be doing that, you're better to keep trying just with diet and exercise and see how it goes. Now when I had the three month test went back I was still pretty unhappy so I went back to him and said no look it's not working, I need a kick start because I was either conscious about what had happened in the education or what had been said and he said yeah ok and he put me on the medication, he also gave me a referral to the diabetes centre... EDACT171

The participant above reported that her average blood glucose levels (BGL) had reduced as a result of using the glucometer to understand her BGLs across the day and in response to her diet. The HbA1c results at 6 months confirmed an improvement in glycaemic control.

Changes in self-management: Impact of the intervention

The majority of participants (n=23) described a change in their daily diabetes management at 3 and 6 months post intervention and attributed these directly to completing the intervention. The specific changes in management practices related to modification of diet (n=13), blood glucose monitoring (n=9), medication management (n=7), prevention of secondary effects (n=4), exercise (n=3), and managing hypoglycaemic events (n=3). Ten participants described changes in two or more areas.

Three people described the impact of the intervention on managing hypoglycaemic events. They now recognised the symptoms and acted upon these:

...the symptoms of when you go into a high or when you go into a low. I had been going into lows and not really doing anything about it and I'd just rest up and maybe have a cup of coffee where I should have been having something a wee bit sweet to get my sugar up but now that I test quite regularly I can go down and you know I've got to have food and I've got to have sweetness just about straight away. EDACT 112.

Descriptions of a change in diet were described by nearly half of the participants (n=13) and related to healthier eating, such as a reduction in carbohydrates:

ED94: I think from my personal point of view it's made my understanding of everything a lot better and I have made some dietary changes.

Interviewer: Right like what 94?

ED94: Like eating more healthy, staying away from things such as pastries and you know like the deep fried foods and stuff.

Interviewer: Right how easy was that to do?

ED94: After the workshop relatively easy.

Glycaemic control had improved at 6 months for this participant, but this pattern was not observed consistently across those who described dietary changes. In addition, three people described having lost weight as a result of the changes in diet.

Nine participants described a change in the frequency of blood glucose self-monitoring following the intervention. Of the nine participants, seven increased the amount of self-monitoring and this gave them a better picture of their glycaemic patterns and relationship to diet and medication. People described the increase in blood glucose monitoring as related to

increased knowledge around why monitoring was important and the link between blood glucose level, diet and health. Two people who were not previously testing their blood glucose levels at all, started as a result of attending the intervention:

ED166: No I thought that was a good workshop that was the most, she explained it well I could understand a hell of a lot more about what the testing systems were, some of the terminology and what it can do for you.

Interviewer: So have you how has that affected how you manage your diabetes or think about your diabetes now?

ED166: Oh it's spurred me onto actually testing myself up to then I hadn't, I had a brand new tester but never took it out of the wrapper but I've got it out the wrapper now got the batteries up and running. I test it if I think I'm going backwards if I suspect I'm going backwards... the nurse said that the best way to do it is test before you have a meal and then test a couple of hours later and that will show you if what you ate is affecting your diabetes before. I didn't know when to test, and what the numbers meant.

Again, the descriptions of improved blood glucose management did not necessarily equate to an improvement in glycaemic control.

Eight participants described a change in medication self-management as a result of the intervention. The changes were mostly related to the timing of taking medication. Five people described now taking Glipizide 30 minutes before their meal rather than at meal times. They described being previously unaware that Glipizide stimulates the release of insulin and therefore the uptake of glucose. Two further participants described now having a better understanding of why medication needed to be taken regularly and not just when remembered

and had instigated prompts to help ensure medication was taken as prescribed (e.g. a pill box). One person described changing their insulin injection technique.

Four people described taking action to manage the potential secondary effects of diabetes for the first time, through eye checks and foot care.

ED163: In terms of things on my feet, you know, sores or anything like that I'm very conscious.

Interviewer: Ok more conscious since the workshop?

ED163: Absolutely, these are, I mean, I'm in landscaping and even I wear gloves now where normally didn't. I sort of ferret around in soil and get cuts and that type of stuff and you know now, I mean have gloves all the time now.

For this participant, working in landscaping, taking precautions such as now wearing gloves at all times had important longer term implications.

Challenges to making changes in the self-management of diabetes

Participants described two main areas, diet and exercise, as issues that challenged them and impacted on their ability to make sustained changes in diabetes management practices and these remained constant at 3 and 6 months post intervention. Two thirds of participants described ongoing difficulty and frustration with eating and diet. Most were aware of how they should be eating but reported self-control, difficulty avoiding certain foods, particularly in social situations, cooking for others, eating on time, and access to vegetables as reasons for not being able to make or continue change. Several participants described frustration that they

had increased their exercise but had not lost weight. A third of participants spontaneously referred to the need for follow-up sessions for ongoing support in self-management:

...there's really no, you know you have that and you feel great for a month or so and then there's no one ED106.

The majority felt that the intervention should be made available to everyone diagnosed with diabetes.

The delivery of the interventions in a group setting was described as highly acceptable by the majority of participants. All participants in the education group described the group setting for the education intervention as highly acceptable and three quarters of those in the education plus ACT group. The majority of participants found the group setting to make an important contribution:

Sense of all being in the same boat, fostered a sense of collegiality EDACT127

Hurrah, I'm normal ED94

Just over a quarter rated the acceptability of the ACT intervention as delivered in a group setting as less acceptable. These participants described feeling that others aired personal issues in too much depth and that they did not identify with others in the group.

Responses to the ACT intervention

The majority of participants described the ACT intervention indifferently; they felt benefit from the ACT intervention was limited when they had already accepted their diagnosis. No-

one described the ACT intervention negatively but nearly half of the group did feel that it did not suit their way of assessing and managing their situation. Others found that they “warmed up” to the ACT intervention:

I initially thought, what is this about? But as we got into it I understood and enjoyed.

EDACT142.

One third of the group felt that the ACT intervention would require more time and practice before it could have a positive effect and before they could assess its impact. The impact of the ACT intervention was explored with the 15 participants who took part in the education plus ACT intervention. The ACT intervention was described as contributing to acceptance of diabetes by one participant only:

Interviewer: What's made you accept your diabetes so well 210?

EDACT210: I think my doctor, you guys and I've done quite a bit of reading about it.

The descriptions of participant's reactions to the ACT intervention provide important insight into how participant's perceived and engaged with the ACT intervention with possible implications on the primary study outcome, glycaemic control.

Discussion

The qualitative evaluation provided insight into the participants' experience of the intervention and the ways in which the intervention influenced outcomes up to 6 months post intervention. Descriptions of the contribution of the interventions to knowledge on diabetes management and the impact on self-management activities were significant. Of particular

note were the number of people who self-identified that the efficacy of medications were previously diminished due their medication regime and the number of participants who started testing their blood glucose levels regularly through understanding of the link between blood glucose, symptoms, diet and longer term impact. Three people were not previously testing their blood glucose levels at all, despite having less than optimal glycaemic control for a prolonged period of time. These changes have the potential to make a significant, positive change in health outcomes for participants. The number of participants who recognised that their current care could be enhanced was significant. The increase in knowledge, in turn, enhanced confidence and participants felt able to discuss their care with their healthcare provider. Discussions with medical practitioners were mostly positive and changes to care made. Three participants did not receive a favourable response from their medical practitioner and whilst one participant persevered and effected a change in care, two participants changed their primary care provider, registering with another medical practitioner as a result.

Descriptions of improvement in self-management activities post-intervention did not always equate to improvement in glycaemic control. A pattern did emerge around the value assigned by participants to the intervention immediately post intervention and outcome at 6 months. This is presented more for discussion than as confirmation of a relationship but is an area for potential follow-up in the future. Initial perception of the value of an intervention could be a predictor of outcome and an area that clinicians can potentially work with clients to explore and enhance.

The changes in diabetes self-management that participants discussed have the potential to underpin significant long term improvements in health outcomes. Intervention to enhance

glycaemic control, even if the reduction is for a short period of time, have been found to effect long term benefits. During the United Kingdom Prospective Diabetes Study (UKPDS) (1), people with type 2 diabetes mellitus who reduced their glycaemic levels to within the recommended levels demonstrated a lower risk of microvascular complications than did those receiving conventional dietary therapy. Post-trial monitoring to determine whether the therapy had a long-term effect on macrovascular outcomes found that despite an early loss of glycaemic differences (with 1 year of the therapy), a continued reduction in microvascular risk and emergent risk reductions for myocardial infarction and death from any cause were observed during 10 years of post-trial follow-up (18).

The increase in knowledge around hypoglycaemia and a direct change in self-management around this also has the potential for significant long term benefits for participants. The short and long-term complications of diabetes related hypoglycemia include precipitation of acute cerebrovascular disease, myocardial infarction, neurocognitive dysfunction, retinal cell death and loss of vision in addition to health-related quality of life issues pertaining to sleep, driving, employment, recreational activities involving exercise and travel (19, 20, 21).

Feedback from participants confirmed increased awareness and understanding of the risk factors, impact and consequences of hypoglycaemia following the intervention and a change in self-management amongst three people who previously were not recognising the symptoms of hypoglycaemia nor aware of how to manage an event.

The impact of delivering the intervention in a group setting was highly supported by the majority of participants. It is unclear whether the effectiveness of the intervention was enhanced by the group interaction. Whilst the majority of participants described being amongst others with the same condition as supportive and valued hearing how others dealt

with the same issues, no-one was able to articulate how these had impacted on change in self-management at 3 and 6 months post intervention either spontaneously or following a prompt by the interviewer. There were some references to others monopolizing the sessions and differential access to group resource (e.g. group leader's attention) may lead some group members to improve and others to make no change or even deteriorate (22). Other potentially important variables that may create within-group dependence might be the average motivation level of group members, presence of natural leaders or role models in the group, scapegoating, cliques, dominating or difficult group members, and the skill of the group leader. Any factor that can vary between groups could be a source of within-group dependence. Exploring these areas through observational qualitative research during the intervention and through interviews post intervention would develop greater insight and knowledge into the impact of the group setting and dynamics specifically on health outcomes.

The main issue that participants highlighted as important but difficult to manage were implementing a change in diet and sustaining a healthier diet. Changes in diet have been identified and described as the primary challenge for people with diabetes for many years (23) and continue to represent an area described as a "struggle" (24). Diet is core to glycaemic control and whilst participants described an increase in knowledge and skills, for example around reading food labels, the key area for ongoing support appeared to be supporting dietary change and maintaining this over time. Providing longer term support around dietary change is recommended as an area of focus for future intervention studies.

In the main trial, glycaemic control was significantly reduced in the education group but not in the education and ACT group. Participants' descriptions of the ACT component of the intervention were mixed. Descriptions of the differences described in knowledge and

management of diabetes, were mostly related to information gained from the education intervention. One explanation for the difference noted in glycaemic control between the two intervention groups could be that whilst the contact time (between the nurses and participants) remained the same in both intervention groups, and both groups received the same information in relation to understanding and managing diabetes, the participants in the education only group had more opportunity to discuss and reflect on the diabetes information within the group. Evidence on the impact on outcomes related to the nature of the delivery of interventions (e.g. pace and variation in material) is not available, however evidence on the positive impact of group interaction on outcomes including HbA1c has been noted (10). The results of this study suggests that the delivery of educational material in relation to diabetes self-management is more effective when time is allocated to discussion, which includes the opportunity to ask questions and to share personal stories in relation to the material presented with peers. It is unclear how effective the ACT intervention would have been if more time for discussion had been available.

Whilst the process evaluation provided insight into the issues participants faced, it did not provide direct evidence relating to experience and outcomes. Whilst it may be that no differences existed in experience by gender or time since diagnosis for example, following intervention, a larger sample would be required. The time and costs associated with a collecting data with a large enough sample to achieve this could be prohibitive for many. The ability to follow participants up over a longer period of time, beyond six months, would have provided further insight into how participants self-managed, and whether benefits gained were sustained or not over time and why.

In the present study, the qualitative data collected through the process evaluation provided important insight into the specific information participants felt they had gained through participation in the interventions, the areas of diabetes management participants changed and the challenges that they faced in making changes. Process evaluations conducted alongside intervention studies can make a valuable contribution to understanding outcomes as measured quantitatively.

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