Journal of Evaluation in Clinical Practice
International Journal of Public Health Policy and Health Services Research

A nurse-led education and cognitive behaviour therapy-based intervention among adults with uncontrolled type 2 diabetes: A randomised controlled trial

Journal:	*Journal of Evaluation in Clinical Practice*
Manuscript ID	JECP-2016-0278.R1
Wiley - Manuscript type:	Original Article
Date Submitted by the Author:	n/a
Complete List of Authors:	Whitehead, Lisa; School of Nursing and Midwifery Crowe, Marie; University of Otago, Centre for Postgraduate Nursing Studies Carter, Janet; University of Canterbury, Psychology Maskill, Virginia; University of Otago, Centre for Postgraduate Nursing Studies Carlyle, Dave; University of Otago, Department of Psychological Medicine Bugge, Carol; University of Stirling, School of Health Sciences Frampton, Chris; University of Otago, Department of Psychological Medicine
Keywords:	healthcare, health services research
Abstract:	Rationale, aims and objectives: Diabetes mellitus is associated with significant morbidity, mortality and escalating healthcare costs. Research has consistently demonstrated the importance of glycaemic control in delaying the onset, and decreasing the incidence, of both the short- and long-term complications of diabetes. Although glycaemic control is difficult to achieve and challenging to maintain, it is key to reducing negative disease outcomes. The aim of this study was to determine whether a nurse-led educational intervention alone or a nurse-led intervention using education and acceptance and commitment therapy (ACT) were effective in reducing HbA1c in people living with uncontrolled type 2 diabetes compared to usual care. Methods: Adults over the age of 18 years, 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 were eligible to participate. Participants were randomised to either a nurse-led education intervention, a nurse-led education plus ACT intervention or usual care. One hundred and eighteen participants completed baseline data collection (N=34 education group, N=39 education plus ACT, N=45 control group). An intention to treat analysis was employed. Results: A statistically significant reduction in HbA1c in the education intervention group was found (p=.011 [7.48, 8.14]). At 6 months, HbA1c was reduced in both intervention groups (Education group -0.21, education and ACT group -0.04) and increased in the control group (+0.32). A positive change in HbA1c (HbA1c reduced) was noted in 50 participants

	overall. Twice as many participants in the intervention groups demonstrated an improvement as compared to the control group (56% of the education group, 51% education plus ACT, and 24% control group. Conclusions: At 6 months post intervention, HbA1c was reduced in both intervention groups with a greater reduction noted in the nurse-led education intervention.

Title: A nurse-led education and cognitive behaviour therapy-based intervention among adults with uncontrolled type 2 diabetes: A randomised controlled trial

Running Title: Intervention for adults with type 2 diabetes

Authors:

Professor Lisa C. Whitehead, PhD, Associate Dean Research, School of Nursing and Midwifery, Edith Cowan University, 270 Joondalup Drive, Joondalup, Western Australia

Professor Marie T Crowe, PhD, Associate Dean (Postgraduate), Centre for Postgraduate Nursing Studies & Department of Psychological Medicine, University of Otago, 4 Oxford Terrace, Christchurch, New Zealand

Professor Janet D Carter, PhD, Head of Department, Department of Psychology, University of Canterbury, 20 Kirkwood Ave, Ilam, Christchurch, New Zealand

Virginia R Maskill, MHealSc., Lecturer, Centre for Postgraduate Nursing Studies, University of Otago, 72 Oxford Terrace, Christchurch, New Zealand

Dr Dave Carlyle, PhD, Senior Lecturer, School of Health Sciences, University of Otago, 4 Oxford Terrace, Christchurch, New Zealand

Dr Carol Bugge, PhD, Senior Lecturer, School of Health Sciences, University of Stirling, Stirling, Scotland, UK

Professor Chris M.A. Frampton, PhD, Biostatistician, Department of Psychological Medicine, University of Otago, 4 Oxford Terrace, Christchurch, New Zealand

Corresponding author:

Lisa Whitehead
School of Nursing and Midwifery
Edith Cowan University
270 Joondalup Drive
Joondalup
Western Australia
Tel 0061 0863042641
Fax 0061 0863042323
Email l.whitehead@ecu.edu.au

Abstract

Rationale, aims and objectives: Diabetes mellitus is associated with significant morbidity, mortality and escalating healthcare costs. Research has consistently demonstrated the importance of glycaemic control in delaying the onset, and decreasing the incidence, of both the short- and long-term complications of diabetes. Although glycaemic control is difficult to achieve and challenging to maintain, it is key to reducing negative disease outcomes.

The aim of this study was to determine whether a nurse-led educational intervention alone or a nurse-led intervention using education and acceptance and commitment therapy (ACT) were effective in reducing HbA1c in people living with uncontrolled type 2 diabetes compared to usual care.

Methods: Adults over the age of 18 years, 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 were eligible to participate. Participants were randomised to either a nurse-led education intervention, a nurse-led education plus ACT intervention or usual care. One hundred and eighteen participants completed baseline data collection (N=34 education group, N=39 education plus ACT, N=45 control group). An intention to treat analysis was employed.

Results: A statistically significant reduction in HbA1c in the education intervention group was found (p=.011 [7.48, 8.14]). At 6 months, HbA1c was reduced in both intervention groups (Education group -0.21, education and ACT group -0.04) and increased in the control group (+0.32). A positive change in HbA1c (HbA1c reduced) was noted in 50 participants overall. Twice as many participants in the intervention groups demonstrated an improvement as compared to the control group (56% of the education group, 51% education plus ACT, and 24% control group.

Conclusions: At 6 months post intervention, HbA1c was reduced in both intervention groups with a greater reduction noted in the nurse-led education intervention.

Key words: Nursing, Randomised Controlled Trial, Type 2 Diabetes Mellitus

Introduction

Daily management of diabetes is essential in controlling blood glucose, however, many people living with diabetes are unable to maintain glycaemic control within the recommended levels (4%-7%, 20-53 mmol/mol) (Peyrot et al., 2013). Diet, exercise, stress, and medication management are the key mediators of glycaemic control (NICE, 2015) and areas strongly influenced by self-management through individual behaviour and action (Wilkinson et al., 2011). The short and long term effects of hyperglycaemia are multiple, including microvascular changes (e.g. retinopathy, nephropathy, and neuropathy) and macrovascular (e.g. heart disease) (WHO, 2010; D'Elia et al., 2011). Uncertainty does remain around the extrapolation of population-based risk reduction estimations to individual predictions (Bejan-Angoulvant et al., 2015), where evidence relating to glycaemic control and long term outcomes have been established through large prospective cohorts. Further, tight glycaemic control can result in harmful effects, for example an increase in hypoglycaemic events (Buehler et al., 2013).

In addition to a global guideline on diabetes management (IDF, 2012), evidence-based guidelines exist across many countries on the treatment of type 2 diabetes (e.g. NICE, 2015) with a consistent focus on patient education, dietary advice, managing cardiovascular risk, managing blood glucose levels and managing the risk of long term complications. Optimal management however, is only thought to be reaching the minority (IDF, 2012) with reasons such as the size and complexity of the evidence-base, the complexity of diabetes care itself, a lack of proven cost-effective resources for diabetes care and diversity in standards of clinical practice cited as driving disparities in clinical care.

The evidence on interventions to support self-management for people with long term conditions is large and attempts to draw together individual study findings to clarify what works, for whom, and in what contexts are available (e.g. Taylor et al., 2014). Interventions directly related to improving the self-management of glycaemic control can be broadly categorised into individual and group based interventions, educational and behavioural interventions, with fewer interventions combining the latter two elements (Jones et al., 2014). A review of all self-management programmes or multicomponent interventions aimed at self-management; education, both group based and individual; behavioural or counselling interventions; and social support for people living with type 2 diabetes (Taylor et al., 2014) reported good evidence that self-management support improves blood glucose control in the short term, with a reduction in mean difference of around 0.4%. The effectiveness of interventions longer term was not as strong, although this was attributed to fewer studies reporting data at 12 months and beyond. The impact of self-management interventions on individuals' QoL and their psychological well-being was not supported, although equally, interventions did not have a detrimental effect. The meta-review was not able to pin point effective elements across interventions, instead suggesting that self-management support may be delivered in many ways, by different professionals and lay people, and that in light of the large number of RCTs and reviews included within the meta-review the failure to reach any conclusion on the optimal model of delivery could reflect that there is no one way (Taylor et al., 2014). The authors suggest that multiple models of delivery may be equally effective and consideration may instead need to be given to other factors which may influence effectiveness, such as the real-world context.

Reviews with a less diverse focus have made recommendations relating to effective elements of interventions. In relation to interventions for women of African/Caribbean

and Hispanic/Latin ethnicity living in industrialised countries, five intervention features (hospital-based intervention setting; group intervention format; situational problem–solving; high intensity, 10 or more sessions; and incorporating dieticians as interventionalists) were found to have a broad impact on the majority of outcomes assessed (diet, anthropometrics, physical activity and HbA1c). A review of behavioural interventions (Health Quality Ontario, 2009), found that the interventions with the largest effects were those with higher baseline HbA1c (≥9%) and in which the interventions were of at least one year in duration. A review and meta-analysis (Jones et al., 2014) on motivational interventions in the management of HbA1c noted that the small number of studies and issues of heterogeneity indicated the need for caution in interpreting the findings and the contribution of motivational interventions may be better assessed by outcomes such as behaviour change.

The current study aimed to contribute to the evidence on the effectiveness of motivational interventions and the interrelation between self-management behaviours and glycaemic control. Acceptance and Commitment Therapy (ACT) is a form of cognitive behavioural therapy. The premise of ACT is the existence of a constant interplay between the internal and external environment affecting the individual's overall functioning (Hayes et al., 2006). Overt behaviour (actions), cognitions (thoughts, beliefs, perceptions), feelings, and physiology are closely and interactively integrated, and could therefore impact the way in which a patient manages his/her diabetes overall. ACT can take a holistic approach to diabetes management including addressing psychological and motivational barriers, acceptance of elements of management and focuses patients on moving in the direction of their values (Gregg et al., 2007).

A previous study comparing an ACT and education intervention with an education only intervention (Gregg et al., 2007) found a significant improvement in HbA1c and in acceptance of diabetes (attitudes and values) and self-management skills for those completing the ACT plus education intervention. Building on this work, it was hypothesised that for people with long-term hyperglycaemia, ACT could raise participants' awareness of the interaction between cognitions, feelings and behaviour and so enable people to better self-manage, leading to improved glycaemic control. The objective of this study was to determine whether a nurse-led educational intervention alone or a nurse-led intervention using education and acceptance and commitment therapy (ACT) were effective in reducing HbA1c in people living with uncontrolled type 2 diabetes compared to usual care.

Methods

Study design

The design was a three arm parallel group randomised controlled trial comparing two active treatment groups with a control condition. This design was chosen over a factorial design (education alone versus ACT alone, versus education and ACT versus neither) on the premise that a certain level of diabetes knowledge would be essential in order for individuals to use the strategies developed through the ACT intervention. The half day education intervention aimed to provide all participants in the group with the same level of knowledge in order to apply the ACT strategies.

Three pairwise comparisons were planned for the analysis of outcomes (education versus control, education plus ACT versus control and education versus education plus ACT). A total of 32 participants were required in each group in order to achieve 80% power to detect as statistically significant (two-tailed $\alpha=0.05$) an absolute

difference between groups at 6 months in HbA1c levels of 0.5%, assuming an SD of 0.7%. The choice of effect size for power analyses was based on data from the UKPDS (Hayes et al., 2013) with a 0.5% difference in HbA1c levels regarded as being clinically significant. The same effect size was chosen for both interventions based on the assumption that a reduction in HbA1c of the same magnitude would be as clinically significant for both groups. The study was granted ethical approval from the Upper South B regional ethics committee, New Zealand, reference number URB/09/08/039.

Recruitment

The inclusion criteria were, a clinical diagnosis of type 2 diabetes for 12 months or more, age 18 years and over and persistent, suboptimal glycaemic control. This was defined as HbA1c >7%, 53mmol/mol in the past 12-18 months, with at least two records of HbA1c > 7%, 53mmol/mol, during this period and 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. Following ethical approval a range of recruitment avenues were employed including radio advertisements, adverts in community newsletters and newspapers and letters sent to patients who met the study criteria through medical centres, across one city in New Zealand. Those people who contacted the research assistant as interested in participation were sent a study information sheet, a consent to be contacted form and a stamp addressed envelope. All those who returned a consent to be contacted form were called by the research assistant to confirm inclusion eligibility and written consent was gained to participate in the study and for the research assistant to contact the medical centre at which they were registered to obtain HbA1c results.

Permuted block randomisation using a computer generated randomisation sequence with a block size of 24 allowed for timely randomisation of participants, where recruitment took place across a 12 month period. A biostatistician completed the randomised allocation. The biostatistician was independent from all other study procedures. The biostatistician sent information on the allocation to the research assistant. Data were collected at baseline, 3 months following baseline, and 6 months following baseline. All study questionnaires were sent by post together with a pre-paid envelope for return.

Description of the interventions

The decision to run the intervention on one day was pragmatic. The intention was to make the intervention as cost effective and convenient as possible for participants and looking to the future, providers who may wish to take up the intervention in practice.

Both 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 diabetes education programmes (Hayes et al., 2006; Gregg et al., 2007; The DESMOND collaborative, 2008). The research team included experienced educators and clinicians who developed a format for delivery that were felt to promote 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 to maintain the same amount of contact time between participants and the nurses. 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 (Gregg et al., 2007). 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.

Fidelity

The fidelity of the intervention was enhanced through the development of a manual for both interventions, all sessions were recorded and reviewed by LW and JC for adherence to the protocol and manuals, and one nurse participated in all of the intervention sessions to enhance continuity of style and content of the sessions.

Control group

The control group were mailed the questionnaires at the same time points as the two intervention groups. Participants in the control group continued to receive routine

diabetes care. Routine care generally comprised visits to the GP/practice nurse as initiated by the patient with an annual invitation by the practice to attend for a health check involving measurement of HbA1c (goal ≤ 7%), weight, blood pressure (goal 13/80), total cholesterol (goal ≤ 4), HDL cholesterol (goal ≥ 1), LDL cholesterol (goal < 2), triglycerides (goal < 1.7), microalbuminuria (ratio < 3), date of last eye examination (at least every 2 years), foot check, sensation and pulses. The control group were not offered the opportunity to participate in an intervention post-trial.

Outcome measures

The primary outcome variable was glycaemic control (HbA1c). The secondary outcome variables were: acceptance of diabetes-related thoughts and feelings and 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.

Glycaemic control

HbA1c was analysed by a local medical laboratory. Participants were asked to either visit their local medical laboratory, widely distributed throughout the city or if required a mobile phlebotomist took the sample at the participant's home. The phlebotomist was blinded to the group allocation of participants. Time points for measurement were at baseline, 3 months and 6 months. A two week window was allowed around the designated data collection time points.

The questionnaires were self-administered. They were sent to the participant's postal address and returned in a stamp addressed envelope. The pack contained

information on who to contact if assistance was required (the research assistant), however, no-one made contact for support to complete the questionnaires.

Acceptance of diabetes

The Acceptance and Action Diabetes Questionnaire (AADQ) (Gregg et al., 2007) is an 11 item Likert type scale to measure acceptance of diabetes-related thoughts and feelings and the extent to which they interfere with valued action (e.g. I avoid thinking about what diabetes can do to me). The scale has demonstrated good inter-rater reliability (Cronbach's α=.94). Scores range from 11-55 with a higher score reflecting greater non-acceptance.

Anxiety and Depression

Anxiety and depression were measured through the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983). The HADS has been used extensively in research and has been shown to have good validity, specificity and sensitivity (Bjelland et al., 2002), and good test-retest reliability (Spinhoven et al., 1997). Although the HADS is a screening tool it correlates well with clinical assessments of anxiety and depression. A score is generated for anxiety and depression, both ranging from 0-21 with a score of 0-7 indicating sub-clinical symptoms, 8-10 possible clinical levels and a score of 11 or over probable clinical levels.

Understanding of the management of diabetes

Understanding of the management of diabetes was assessed by a sub-scale of the Diabetes Care Profile (DCP; Cronbach's α=.60-.95) (Fitzgerald et al., 1996). The DCP comprises 14 subscales in total. The understanding subscale comprises 10

items and explores understanding of key aspects of the management of diabetes e.g. “How do you rate your understanding of diet and blood sugar control?” Reliability was explored in two large studies, a community study (n=440) and medical centre study (n=352). Reliabilities (cronbach’s alpha) of the understanding subscale were reported as .92 and .92 respectively (Fitzgerald et al., 1996). Scores range from 10-50, with a higher score indicating better self-rated understanding of diabetes.

Diabetes treatment satisfaction

The diabetes treatment satisfaction questionnaire (DTSQ) (Bradley, 1994) was used to measure satisfaction with diabetes treatment. The 6 item scale assesses treatment satisfaction and two items assess perceived frequency of hyperglycaemia and hypoglycaemia. Ceiling effects have been noted with the DTSQ and the DTSQc was developed to overcome these (Bradley, 1999). The authors recommend using the DTSQ first to anchor the findings, followed the DTSQc to explore how people’s satisfaction with perceived hypoglyacaemia and hyper glycaemia have changed. The DTSQ has been widely used and is recommended by the World Health Organisation (WHO) and the International Diabetes Federation as useful in assessing outcomes of diabetes care (Bradley & Gamsu, 1994). On the DTSQ, each of the 8 items are scored on a scale of 0-6 with a higher score indicating greater satisfaction. For the DTSQc, each item is scored on a scale of -3 to +3 with a higher score indicating greater satisfaction.

Diabetes self-care activities

The summary of diabetes self-care activities measure was used to assess self-care activity (Toobert et al., 2002). Three of the 8 subscales; general diet, exercise and blood glucose testing were used in this study. The inter-rater reliability, measured by

means of the Cronbach's alpha coefficient, ranged from 0.66 to 0.80 for the three sub-scales independently (30, 31) and a Cronbach's alpha of 0.71 for the three subscales collectively as measured using all baseline data from this study.

The sub-scale general diet, includes two questions: How many of the last 7 days have you followed a healthy eating plan? And over the past month, how many days/week have you followed your eating plan? The exercise component questions on how many of the last 7 days did you participate in at least 30 minutes of physical activity? On how many of the last 7 days did you participate in a specific exercise session other than what you do around the house/work? And the blood glucose subscale, On how many of the last 7 days did you test your blood sugar? and On how many of the last 7 days did you test your blood sugar the recommended number of times? The derived scores reflect the number of days within a week recommended activity related to diet, exercise and blood glucose monitoring have been followed. The range is 0-42, with a higher score reflecting greater self-management.

Data analysis

Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS), version 19 (SPSS In., Chicago, IL, USA). Standard descriptive statistics were used to summarise demographic and clinical characteristics for the randomised groups. Analyses were carried out on an intention-to-treat basis which included all participants who completed the baseline questionnaires, a blood test for HbA1c and in the intervention groups, attended the workshop. Missing values were handled according to the guidelines for each scale. An analysis of covariance (ANCOVA) was used to compare the HbA1c levels at 6 months between randomised groups where the randomised group was treated as a fixed factor and the baseline

value for HbA1c (taken within 3 months of commencing the study) as a covariate. If a significant effect ($p<0.05$) of randomised group was identified from the ANCOVA then pairwise comparisons of each intervention group with the usual care were undertaken. ANCOVA was also used to compare the secondary outcomes using randomised group as a fixed factor and the relevant baseline level as a covariate.

Results

Recruitment outcomes and sample description

Over a twelve month period, 303 people responded and following assessment for eligibility, 172 people who met the study criteria were approached. One hundred and fifty seven participants with glycaemic control outside of the recommended range for over 12 months gave informed consent and were randomised to one of three groups, education, education plus ACT, or usual care (control). In total, 51 participants were randomised to the education only intervention, 54 to the education plus ACT intervention and 52 to the control group. A total of 34 participants declined to participate post-randomisation; 14 participants had moved away or were no longer contactable, and 25 participants had changed their minds, mostly related to lack of time.

Table 1 to be inserted here

The differences in baseline characteristics across the three randomised groups were not significantly different (table 1).

At 6 months, 21 people did not complete a blood test for HbA1c level and 12 participants did not complete and return the questionnaires. Baseline analysis found

no difference between those lost to follow-up and those who completed the study. Intention to treat analysis was conducted. Figure 1 outlines the trial profile.

Figure 1 to be inserted here

Effects on glycaemic control

At 6 months, HbA1c was reduced in both intervention groups (Education group -.21, education plus ACT group -.04) and increased in the control group (+.32). The primary outcome results are presented in tables 2-3.

Table 2 to be inserted here

An ANCOVA using HbA1c pre-scores as the covariate found significant differences between the participants' HbA1c at 6 months ($F(2,114)=3.29$, $p=.04$). Planned contrasts found no statistical difference in HbA1c at 6 months between the control group and the education plus ACT group ($p=.079$ [7.61,8.23]). The mean difference in HbA1c between the control group and education intervention group at 6 months was statistically significant ($p=.011$ [7.48, 8.14]). Exploring change in HbA1c by direction (positive, none or negative) showed that, proportionally, twice as many participants in the intervention groups demonstrated a reduction in HbA1c compared to the control group (table 3).

Table 3 to be inserted here

A positive change in HbA1c (HbA1c reduced) was noted in 50 participants overall (56% education group, 51% education and ACT, and 24% control group).

Effects on secondary and safety outcomes

The analysis of the secondary measures are presented in table 4. No significant differences between the conditions in participants' acceptance of diabetes (AADQ), anxiety and depression, understanding of diabetes, satisfaction with treatment or satisfaction with blood glucose control. Close to significant between group differences were noted in self-management practices. Self-management activities improved in the education plus ACT group but decreased in the education group to a result reflective of the control group.

Table 4 to be inserted here

Potential adverse events such as episodes of hypoglycaemia were not systematically recorded. Based on episodically reported information, no serious events of hypoglycaemia were recorded in either study group.

Discussion

In this study, ~~T~~the HbA1c level was reduced in both intervention groups and this change was statistically significant in the education only group at 6 months post intervention. No effects on secondary outcomes were found. The results of this study indicate that a one day nurse-led group intervention can have an impact on diabetes management up to 6 months post intervention. An earlier study (Gregg et al., 2007) found a significant decrease in HbA1c in an education plus ACT group and a significant change (improvement) in acceptance of diabetes as measured by the AADQ and in self-management. In this study no significant changes on any variable were noted for the education plus ACT group as compared to the control group or

education only group. Although the current study did not seek to replicate the Gregg et al study, we did use similar principles and material in developing the intervention. A difference in the characteristics of participants by mean years since diagnosis was noted between the studies, 5.3 years (Gregg et al., 2007) vs 10.03 years in the current study. It could be hypothesised that the difference in outcome between the studies was related to time since diagnosis and that this ~~can~~ influenced the ability to change attitudes and values towards diabetes. The potential impact of time since diagnosis on study design and outcome requires further consideration.

In the interventions in this study, and especially so in the education plus ACT group, participants were asked to deal with attitudes towards diabetes and self-care, to observe negative feelings and to reflect on values in life. While this could be challenging and result in increased worry and anxiety about life and diabetes, participants showed stable or improved scores on all psychological variables.

Any intervention seeking to reduce HbA1c levels raises concern around increase of hypoglycaemic episodes. In this study, t~~T~~here was no evidence that participants experienced episodes of hypoglyacaemia and no reports of a medical emergency related to hypoglycaemia, although we did not specifically collect data on blood glucose levels outside of the primary measure of HbA1c nor did we directly seek feedback on experiences of hypoglycaemia nor of fear of hypoglycaemia.

Both individual and group settings have been used for cognitive-behavioural interventions, with no definitive conclusion as to which setting is more effective (Fan & Sidani, 2009; Kulzer et al., 2007). The literature on educational interventions for diabetes self-management favours the group setting (Andersen et al., 2005),

although the specific aspects of group intervention that are effective have not been isolated. It is unclear how the group process contributed to outcomes and this requires further investigation.

The delivery of interventions in a group setting has obvious cost advantages in the clinical setting. Thise study has also shown that a nurse-led intervention is effective in reducing HbA1c. The nurses in this study did not receive costly training and although specialists provided oversight, they did not contribute to the intervention. These findings are of significance in the clinical setting where the ability to draw on staff involved in the regular care of the patient in the primary care setting is both cost-effective and more realistic in terms of embedding interventions into clinical practice. What is not known is whether the input of specialists or of peer leadership would have been more effective and remains an area for future exploration.

It is unclear how long the positive effects of the interventions on glycaemic control observed in this study will last. Taylor et al (2014) noted diminished effects at 12 months and beyond amongst intervention studies to improve self-management of type two diabetes. beyond the conclusion of a research study. Based on earlier literature, it is likely that maintenance sessions would be required to sustain the effect shown (Canadian Diabetes Association, 2015). Connecting with community partners and other chronic care model programmes running in the community has proven to be a successful adjunct to cognitive-behavioural interventions, allowing the effects to be sustained as far out as 3 years post intervention (Piatt et al., 2010; Gambling & Long, 2010; Kim et al., 2009). Incorporating booster sessions enhances the effectiveness of self-management interventions however, healthcare providers are challenged in providing continued self-management support over time and as

needed by individuals. Reaching patients between visits and tailoring information and support to meet specific needs could be addressed more successfully through the use of technology (e.g. the internet, web-based education, text messaging, email, automatic telephone reminders, telehealth/telephone education and reinforcement). Although the evidence on the effectiveness of e-health is mixed, it is gathering momentum and has been proven effective in the management of HbA1c (e.g. Hamine et al., 2015; Kirwan et al., 2013) and offers a time-efficient means of providing ongoing support.

In summary, the nurse-led education intervention is a promising approach in improving outcomes for those with type 2 diabetes and long term, less than optimal glycaemic control. Further research to explore the value of group sessions over individual interventions, the relative benefits of ACT versus education, the impact of maintenance sessions and follow-up over a longer time period would enhance understanding of the value and role of interventions to support glycaemic control.

Acknowledgements

The authors have no relevant conflicts of interest to disclose.

L.W. wrote the manuscript and researched data. M.C., J.C., V.M., D.C., C.B., C.F. contributed to the design and conduct of the study, analysis of data, and write-up.

The study was funded by the Strategy to Advance Research in Nursing and Allied Health (STAR). The funder did not play any role in the conduct of the study.

References

1. Peyrot M, Burns KK, Davies M, Forbes A, Hermanns N, et al. Diabetes Attitudes Wishes and Needs 2 (DAWN2): a multinational, multi-stakeholder study of psychosocial issues in diabetes and person-centred diabetes care. Diabetes Res Clin Pr 2013; 99: 2,174-84.
2. NICE (2015) Type 2 diabetes in adults:management. Accessed from http://www.nice.org.uk/guidance/ng28, 7th January 2016.
3. Wilkinson A, Whitehead L, & Ritchie L. Factors influencing the ability to self-manage diabetes for adults living with type 1 or 2 diabetes Int J Nurs Stud 2011; 51: 1, 111–122.
4. World Health Organisation. Causes of death 2008. Data sources and methods. Geneva 2010. Available from http://www.who.int/healthinfo/global_burden_disease/cod_2008_sources_methods.pdf Accessed 15.1.16.
5. D'Elia JA, Bayliss G, Roshan B, Maski M, Gleason RE, Weinrauch LA. Diabetic microvascular complications: Possible targets for improved macrovascular outcomes. Int J Nephrol Renovasc Dis 2011; 4:1-15.
6. Bejan-Angoulvant T, Cornu C, Archambault P, Tudrej B, Audier P, Brabant Y, Gueyffier F, Boussageon R. Is HbA1c a valid surrogate for macrovascular and microvascular complications in type 2 diabetes? Diabetes Metab 2015; 41(3):195-201. doi: 10.1016/j.diabet.2015.04.001.
7. Buehler AM, Cavalcanti AB, Berwanger O, Figueiro M, Laranjeira LN, Zazula AD, Kioshi B, Bugano DG, Santucci E, Sbruzzi G, Guimaraes HP, Carvalho VO, Bordin SA. Effect of tight blood glucose control versus conventional control in patients with type 2 diabetes mellitus: a systematic review with

meta-analysis of randomized controlled trials. Cardiovasc Ther. 2013 Jun;31(3):147-60. doi: 10.1111/j.1755-5922.2011.00308.x.

8. IDF (2012) Global guideline for type 2 diabetes management. Accessed from http://www.idf.org/sites/default/files/IDF-Guideline-for-Type-2-Diabetes.pdf, 7th January 2016.
9. Taylor SJC, Pinnock H, Epiphaniou E, Pearce G, Parke HL, Schwappach A, Purushotham N, Jacob S, Griffiths CJ, Greenhalgh T, Sheikh A. A rapid synthesis of the evidence on interventions supporting self-management for people with long-term conditions: PRISMS - Practical systematic Review of Self-Management Support for long-term conditions. Southampton (UK): NIHR Journals Library; 2014 Dec.
10. Jones A, Gladstone BP, Lübeck M, Lindekilde N, Upton D, Vach W. Motivationalinterventions in the management of HbA1c levels: a systematic review and meta-analysis. Prim Care Diabetes 2014;8(2):91-100. doi: 10.1016/j.pcd.2014.01.009.
11. Health Quality Ontario. Behavioural interventions for type 2 diabetes: an evidence-based analysis. Ont Health Technol Assess Ser 2009; 9 (21):1-45.
12. Hayes S C, Luoma J, Bond F, Masuda A, & Lillis J. Acceptance and commitment therapy: Model, processes, and outcomes. Behaviour Res Ther 2006; 44, 1–25.
13. Gregg J, Callaghan G, Hayes S, Glenn-Lawson J. Improving Diabetes Self-Management Through Acceptance, Mindfulness, and Values: A Randomized Controlled Trial. J Consult Clin Psychol 2007; 75: 2, 336–343.
14. Hayes AJ, Leal J, Gray AM, Holman RR, Clarke PM UKPDS Outcomes Model 2: a new version of a model to simulate lifetime health outcomes of patients

with type 2 diabetes mellitus using data from the 30 year United Kingdom Prospective Diabetes Study: UKPDS 82 Diabetologia 2013;56:1925-1933

15. The DESMOND collaborative, 2008. http://www.desmond-project.org.uk/index.php accessed 13.6.15.
16. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatr Scand. 1983 Jun;67(6):361-70.
17. Bjelland I, Dahl AA, Haug TT, Neckelmann D. The validity of the Hospital Anxiety and Depression Scale. An updated literature review. J Psychosom Res. 2002; 52(2):69-77.
18. Spinhoven P, Ormel J, Sloekers PP, Kempen GI, Speckens AE, Van Hemert AM. A validation study of the Hospital Anxiety and Depression Scale (HADS) in different groups of Dutch subjects. Psychol Med. 1997;27(2):363-70.
19. Fitzgerald J T, Davis W K, Connell C M, Hess G E, Funnell M M, Hiss R G. Development and validation of the Diabetes Care Profile. Evaluation of Health Professions; 1996: 19, 208–230.
20. Bradley C. *Diabetes treatment satisfaction questionnaire* in: Handbook of Psychology and Diabetes, Bradley C. (ed.), Chur, Switzerland: Harwood Academic Publishers, 1994.
21. Bradley C (1999) The Diabetes Treatment Satisfaction Questionnaire (DTSQ): change version for use alongside status version provides appropriate solution where ceiling effects occur. Diabetes Care 1999; 22: 3, 530-2.
22. Bradley C, Gamsu DS. Guidelines for Encouraging Psychological Well-being. Report of a Working Group of the World Health Organization Regional Office for Europe and International Diabetes Federation European Region St Vincent Declaration Action Programme for Diabetes. Diabetic Medicine 1994; 11:5, 510-516. DOI: 10.1111/j.1464-5491.1994.tb00316.x

23. Toobert D J, Glasgow R E, Hampson S. The summary of diabetes self-care activities measure: Results from seven studies and a revised scale. Diabetes Care 2002; 23: 943–950.
24. Fan L, Sidani S. Effectiveness of Diabetes Self-management Education Intervention Elements: A Meta-analysis. Canadian Journal of Diabetes 2009; 33: 1, 18–26.
25. Kulzer B, Hermanns N, Reinecker H, Haak T. Effects of self-management training in Type 2 diabetes: a randomized, prospective trial. Diabetic Medicine 2007; DOI: 10.1111/j.1464-5491.2007.02089.x
26. Anderson RM, Funnell MM, Nwankwo R, Gillard ML, Oh M, Fitzgerald JT. Evaluating a problem-based empowerment program for African Americans with diabetes: Results of a randomized controlled trial. Ethnicity & Disease. 2005; 15: 4, 671–678.
27. Canadian Diabetes Association. Self-management Education available from http://guidelines.diabetes.ca/Browse/Chapter7. Accessed 11.6.15.
28. Piatt GA, Anderson RM, Brooks MM, et al. 3- year follow-up of clinical and behavioral improvements following a multifaceted diabetes care intervention: results of a randomized controlled trial. Diabetes Educ 2010;36:301–309.
29. Gambling T, Long AF The realisation of patient-centred care during a 3-year proactive telephone counselling self-care intervention for diabetes. Patient Educ Couns. 2010 80; 2:219-26. doi: 10.1016/j.pec.2009.11.007. Epub 2009 Dec 16.
30. Kim M, Han H, Song H. A community-based, culturally tailored behavioral intervention for Korean Americans with type 2 diabetes Diabetes Educ 2009; 35: 986 994.

31. Hamine S, Gerth-Guyette E, Faulx D, Green B, Ginsburg A. Impact of mHealth Chronic Disease Management on Treatment Adherence and Patient Outcomes: A Systematic Review. J Med Internet Res. 2015; 17: 2, e52.
32. Kirwan M, Vandelanotte C, Fenning A, Duncan M. Diabetes Self-Management Smartphone Application for Adults With Type 1 Diabetes: Randomized Controlled Trial. J Med Internet Res. 2013; 15: 11. e235.

Figure 1: Trial profile

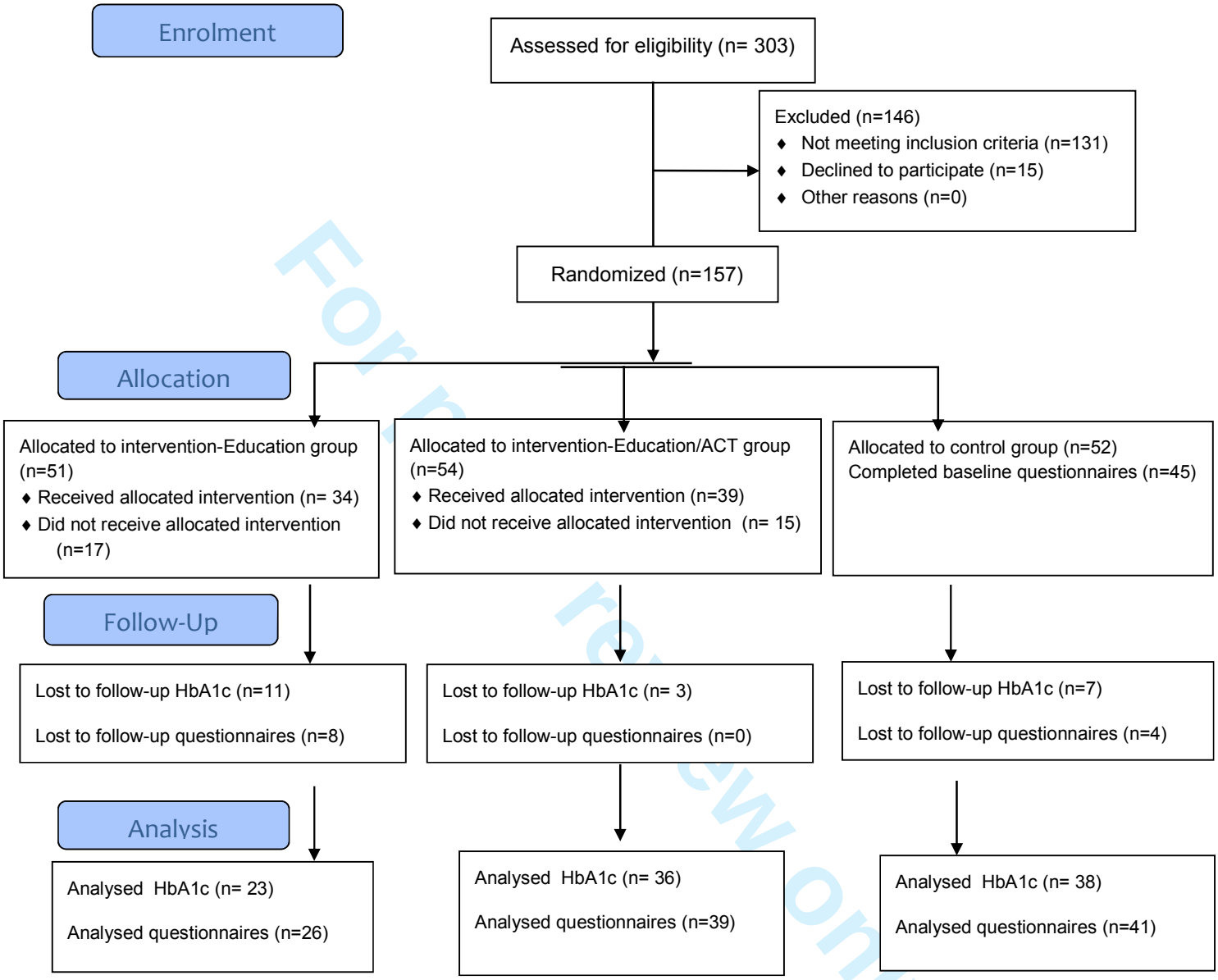

Table 1. Demographic details

	Education (N=34)		Education & ACT (N=39)		Usual Care (N=45)	
Age mean years (SD)	53.76 (8.68)		56.1 (6.91)		56.4 (6.97)	
Gender	N	%	N	%	N	%
Male	20	59	17	44	26	58
Female	14	41	22	56	19	42
Ethnicity						
NZ European	24	71	35	90	36	80
Maori	3	9	0	0	5	11
Time since diagnosis						
<5 years	13	38	10	26	14	31
5-9 years	9	26	14	36	14	31
>10 years	12	36	15	38	17	38

Table 2. HbA1c levels at baseline, 3 months and 6 months

	Baseline	3 months	6 months	Difference
Usual care	8.08	8.13	8.40	+0.32
Education	8.13	7.80	7.92	-0.21
Education + ACT	7.78	7.73	7.74	-0.04

Table 3. Direction of change in HbA1c

	Direction of change			
	Positive N (%)	None N (%)	Negative N (%)	Total
Control	11 (24)	4 (9)	30 (67)	45
Education	19 (56)	2 (6)	13 (38)	34
Education + ACT	20 (51)	1 (3)	18 (46)	39
	50	7	61	118

Table 4: Effects on secondary outcome measures

	Pre-treatment			Post-treatment (6 months follow-up)				
	M	SD	95 % CI	M	SD	Intra-group difference	95 % CI	F-test (ANCOVA between groups effects)
Acceptance of Diabetes								
Usual care	67.8	32.02	56.17-79.70	70.53	33.36	-1.34	63.10-77.26	
Education	71.76	28.77	56.64-81.26	76.42	32.97	-4.66	69.19-84.75	
Education + ACT	68.03	28.17	58.08-85.61	69.03	27.54	-1	59.36-75.56	p<0.21
Anxiety								
Usual care	5.6	4.57	4.35-7.31	5.59	4.9	0.01	4.04-7.13	
Education	4.62	4.13	2.98-6.48	4.81	3.82	-0.19	3.27-6.35	p<0.98
Education + ACT	5.5	3.64	4.30-6.70	5.54	3.66	-0.04	4.24-6.65	
Depression								
Usual care	4.1	3.6	3.23-5.55	3.49	3.01	0.61	2.64-3.72	
Education	3.53	2.82	2.25-4.52	2.73	2.68	0.8	2.69-3.93	p<0.95
Education + ACT	3.87	3.45	2.73-5.0	3.33	3.21	0.54	2.66-3.83	
Understanding								
Usual care	3.4	1.31	2.92-4.10	3.7	1.72	-.03	3.15-3.94	
Education	3.09	0.72	2.75-3.40	4.06	1.68	-0.97	3.50-4.40	p<0.53
Education + ACT	3.13	0.78	2.85-3.50	4.03	1.23	-0.9	3.68-4.53	
DTSQ- Satisfaction								
Usual care	13.13	2.95	24.37-28.69	6.83	6.71	-6.21	6.47-11.24	
Education	12.13	4.5	20.03-28.47	8.12	8.78	-4.62	7.15-12.72	p<0.60
Education + ACT	13.67	3.16	24.80-29.90	8.85	5.13	-5.57	6.26-11.47	
DTSQ-Blood glucose control								
Usual care	.94	1.21	3.12-4.88	.41	2.06	1.45	-.039-1.22	
Education	1.93	1.08	2.84-4.86	-0.18	2.24	1.97	-1.24-0.86	p<0.48
Education + ACT	1.88	1.0	2.96-4.58	0.62	2.23	1.27	-0.23-1.47	
Self-management								
Usual care	9.77	4.62	8.33-12.31	9.73	4.78	0.04	8.74-11.36	
Education	10.30	4.25	9.04-12.58	9.5	5.16	0.83	7.83-11.09	p<0.07

Education + ACT	10.81	4.78	12.05-13.28	12.17	4.05	-1.36	10.39-13.25	