

# **DHBRF Translational Research**

## **Final Report**

### **Krebs 09-584: NZ Group-based Self-Management Education for Patients / Whanau with Type 2 Diabetes**

#### **Contents:**

1. Original Proposal
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## **1. Original Proposal:**

### **Research Topic**

Development of a structured, New Zealand focussed group-based diabetes self-management education (DSME) programme for people, families and whanau with type 2 diabetes (T2DM).

### **Aim**

To develop and trial an evidence based, New Zealand focussed diabetes self-management education (DSME) programme for people with T2DM that can be delivered to groups in different settings.

### **Background**

Diabetes affects an estimated 200,000 people in NZ (approx 4% of total population) and the prevalence is projected to increase by around 45% between 2001 to 2011<sup>1</sup>. Recent evidence shows the prevalence of diabetes was 2.8 times greater for Maori and 4.1 times greater for Pacific people compared with Europeans<sup>2</sup> with higher rates of complications.

Management of type 2 diabetes (T2DM) requires a co-ordinated approach to glycaemic control and cardiovascular risk management with evidence from studies such as the UKPDS demonstrating improved outcomes with good control<sup>3,4,5</sup>. However, this is frequently not achieved in practice for a variety of organisational, health professional and patient factors. Data from the “Get Checked” programme (collated by the Wellington Regional Diabetes Trust) for 3140 individuals with a least 5 annual reviews, show that whilst rates of statin use are improving with associated benefits in lipid profiles, little impact is being made on weight, glycaemic control and blood pressure<sup>6</sup>. Similar data exist from the Otago Diabetes Project where improvements in lipid profiles and statin prescribing are offset by deteriorating glycaemic control, overweight and obesity<sup>7</sup>. It is conceivable that deteriorating glycaemic control over time in T2DM patients may, to some extent, be explained by failure to comply with dietary advice and not entirely explicable by the progressive disease process.

For most patients with T2DM marked behaviour change is necessary before recommended lifestyle patterns are achieved. However, facilitating behaviour change requires the patient to move through the Stages of Change and to actively manage their diabetes. Part of this process is to increase their self-efficacy and develop self-management skills, once this occurs people with T2DM are able to improve their diabetes control<sup>8</sup>. Internationally there is a movement towards group based education programmes for people with Type 2 diabetes that are theoretical based using cognitive reframing<sup>9</sup>. Group based DSME programmes such as DAFNE<sup>10</sup>, DESMOND<sup>9</sup> and X-PERT<sup>8</sup> have been shown to be effective at increasing self-management skills in patients with T2DM with

resultant improvements in diabetes and blood pressure, and reduced risk of diabetes related complications, cardiovascular disease and death<sup>11</sup>.

The evidence for the effectiveness of group-based DSME was reviewed by Deakin *et al* in a Cochrane review<sup>11</sup>. This included randomised controlled and controlled studies, which had at least 6 months follow up. Eleven studies involving a total of 1532 participants were included in a meta-analysis. The results found a clinically and statistically significant reduction in HbA1c by 1.0% at 2 years and body weight by 1.6kg at 12-14 months, and improved diabetes knowledge. Therefore there is clear evidence of benefit for group-based DSME in an international setting. However none of these programmes have been developed or critically appraised in New Zealand, and more particularly in Maori or Pacific populations. Whilst a randomised controlled trial comparing DSME with usual care may be ideal, translating this international data and assessing its impact in a New Zealand context is an appropriate and valid alternative. This is in line with the principles of this grant, and fits with the model of translational research where the existing evidence is summarised, local barriers to implementation identified, performance measured and implementation ensured<sup>12</sup>.

This proposed project will translate current evidence to improve diabetes self management by using existing tools and redesigning them for the unique New Zealand population and cultural mix. The study will assess the acceptability, and clinical, lifestyle and psychosocial effect of group-based DSME utilising the new toolkit in a variety of population groups.

**Design/Methods:** This study will be in two phases.

- Phase 1. Develop and pilot the toolkit in selected groups.
- Phase 2. Longitudinal trial of programme selected primary care environments.

**Phase 1.** Prior to the commencement of funding from this grant, the research team will have completed the literature review and national consultation process to summarise the current best evidence-based education programme. The information from this will shape the development of a toolkit for use in this study. However from the review to date the following is clear. There are several key components to the programme which will be;

- group-based, and include family and whanau
- deliverable in primary care / community setting
- deliverable by primary care team and/or appropriate community workers (eg Maori health providers)
- module based to enable individualisation of components to each setting

The programme is likely to run in weekly 1-2 hour sessions over four to six weeks. Flexibility will be built into this. The content of the programme modules will cover at least;

- What is diabetes mellitus
- Lifestyle management of diabetes including diet, physical activity and smoking
- Role of medication
- Management targets, including interpreting of own blood pressure, blood and urine tests.
- Ability of self-management to influence diabetic control.

The programme will consider different ethnic foods, culture and learning preferences and will have separate “toolkits” that will enable the programme to be used for Maori, Pacific, European and other specific ethnicity groups. These specific modules for Maori and Pacific and other groups will be developed, with integral consultation with community groups facilitated by Sera Tapu-Taala (Pacific) and Howard Metekingi (Maori).

A trainer handbook will be developed to ensure consistency of the programme. It will be used by practice nurses, community dietitians and other relevant health workers, to facilitate quality control and allow auditing of the programme. Tools will be duplicated in Maori and it is hoped that this will also be possible in Pacific languages.

The programme will be piloted in groups of 10 participants in several settings including; a general practice in Wellington, Maori provider in Porirua and Pacific provider in Wellington. Assessment will be made of the appropriateness of the toolkit, the acceptability of the programme to patient, family and whanau, and the ease of use of toolkit by facilitator/ provider. This will include focus group discussions and questionnaires. The toolkit will then be modified according to the feedback obtained.

**Phase 2.** Is a longitudinal assessment of the impact of the programme when in different population groups in Wellington and Dunedin. Participants will have a diagnosis of type 2 diabetes > 6 months and < 5 years. They will take part in a group-based education programme utilising the toolkit developed above. Sessions will be delivered in a primary care environment which may include General Practice rooms, Marae, Community hall or church or other suitable location. Sessions will be delivered by an appropriate person from within the specific healthcare environment. For example a practice nurse, community dietitian, Maori or Pacific health worker. In each of these settings the facilitator of the session will select tools from the toolkit to individualise sessions, but ensuring that the principles of each session are covered.

Based on previous studies a total of 60 subjects will be recruited for this longitudinal analysis. This will include 20 in each of Maori, Pacific and General groups. Groups will be recruited to include up to 10 participants. Data will be analysed for change over time for the combined population with a secondary subgroup analysis.

### **Main Outcome Measures**

The following routine clinical data will be collected from the primary health care records at baseline, 3 months, 6 months and 9 months. The Healthcare providers of each of the participants will be reminded of the importance of collecting this data, and followed up by the researchers.

- Anthropometric data (height, weight and waist circumference)
- Blood Pressure
- Blood tests (HbA1c, Fasting lipid profile)
- Urinary Microalbumin:creatinine ratio
- Smoking status

All participants will be asked to complete validated questionnaires at baseline, after the intervention at 3 months and at the end of 9 months to assess: **Lifestyle;** dietary intake, physical activity, medication adherence including self monitoring of blood glucose, medication, and smoking status. **Psychosocial outcomes;** well-being, anxiety, depression, attitude, knowledge towards diabetes and empowerment.

**Translatability:** This research is designed to translate existing international knowledge into a New Zealand context. Specifically to create a programme which can be utilised in the wider community setting, tailored for specific groups within the population but flexible and interchangeable to meet the needs of a wide variety of groups. As such the findings of the research will be directly and immediately translatable for implementation in broader national primary care.

**Dissemination:** The research group are well placed to disseminate the findings of the research because of the broad representation. First the findings will be communicated with the participants and their primary care health workers. The findings will be disseminated through Compass Health to all of the PHO's that they provide management services for, to the DHB and to the Ministry of Health. Reports will be made to the local diabetes teams in Wellington and Dunedin, and to Diabetes NZ. Through Howard Metekingi, findings will be disseminated to Maori and Maori health providers and through Sera Tapu-Taala to Pacific and Pacific health providers. The findings will also be presented at relevant national and international meetings, and submitted for publication to peer reviewed journals.

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## 2. Challenges and Delays:

The successful completion of this project has been hampered by a number of delays and challenges. As a consequence the work is still ongoing. Final data collection will now be completed during September 2011 with database lock on 30<sup>th</sup> Sept. Following this, data analysis and dissemination will be possible.

The delays and challenges that have occurred are:

- The initial contract was delayed because of need for clarification of overhead rates for the DHB, and other minor legal issues.
- The final ethical approval was delayed
- The number of participants for the second phase of the study was increased from 60 to 100 during the revision of the study design at time of ethical approval. This had obvious implications for meeting recruitment timeline targets.
- The interface with primary care was difficult, despite considerable effort by investigators who included representatives from primary care. (see below)
- Recruitment was challenging for a number of reasons;
  - The initial main recruitment drive coincided with the swine flu epidemic. This meant that General Practitioners were less able to give consideration to identifying participants.

- The PHO in Dunedin initially identified as a locality for participation underwent restructuring and was no longer able to take part.
- Considerable time and effort was then put in to establishing alternative localities. Negotiations with PHOs in the Hutt Valley were promising but eventually unsuccessful. Finally a site was established in Oamaru and in the Wairarapa, however there were considerable delays in establishing these sites.
- Getting blood tests done. The design of this translational project was to utilise existing clinical data being collected by general practice as part of routine good clinical care. There was agreement from PHO management for this process, however there were major challenges with this approach once the study started.

There was significant overlap with another project (Krebs 09-586: Preventing diabetes in people with acute coronary syndrome and hyperglycaemia) in terms of the challenges faced in this project. A final report for that project has been submitted. The main issue was successful engagement with primary care. There were several representatives from primary care included in the team of investigators, with medical, nursing and management roles. The whole project was planned with this in mind and early discussion was undertaken with the principal PHO in the Wellington region. The research team also met with, and presented to, the combined PHO clinical governance committee, obtaining strong support for the study and understanding that the clinical measurements would be part of good clinical practice, and would be enabled through enrolment of patients in “care plus”. The investigators also included information about the study in local presentations to General Practitioner meetings.

As patients were enrolled in the study specific letters were sent to the General Practitioner. This was to ensure that the practice knew the patient was enrolled and the expectations for that patient. Patients were also given very clear written instructions outlining the expectations for their follow up.

Despite the considerable effort put in to all of these aspects, engagement of primary care at individual general practitioner level was poor. There was a clear disconnect between the understanding of the PHO at management level and the willingness of many practices or General Practitioners to engage in the process. There was also very poor follow through by patients to engage in the level of follow up requested. This was despite the informed consent process, further verbal discussion and written material. This aspect of the study has limited the ability to answer the primary aim, but is a very important finding in itself. This is particularly relevant as one of the aims of the self management programme was to empower patients with knowledge about the importance of monitoring tests and what the results mean and the targets being set. Lack of patient engagement in the follow up is an important finding. As a consequence the data for 3 and 6 months is very compromised. Once again this is an important finding in itself. To ensure that a better capture of data occurred at 9 months, where patients had not seen their GP, research staff independently facilitated the collection of data at this timepoint, with limited success.

All of these delays and challenges have meant that the project has not been completed on time. The investigators are making one final attempt in September to collect the outstanding data. Despite the difficulties in data collection we are confident that meaningful results will ensue.

### **3. Study Outcomes to Date:**

At the time of writing this final report, the final data collection for the last group of participants is still ongoing. This will be completed during Sept 2011, with database lock on Sept 30<sup>th</sup>. Therefore at this time there are no final results to report.

**Phase 1. Toolkit development and Pilot Study**

This has been successfully completed. The toolkit was developed by Eirean Gamble as her Masters project. Eirean is in the final stages of preparing her thesis for examination and will submit in September 2011.

The piloting of the toolkit and training of group facilitators went well. The material was well received and focus group discussions informed minor changes in the toolkit material

**Phase 2.**

This part of the project is ongoing. Ninety eight participants were recruited to take part in the education programme. There were 14 groups run with between 5 and 15 participants in each. Of these, 11 were in the Wellington region, one in Oamaru and two in Wairarapa. Groups were mostly of mixed ethnicity, One group was specifically in Maori and two groups facilitated through the Indian community.

Anecdotal feedback from participants has been universally positive. A letter has been received from participants in Wairarapa in support of the programme. (see attached)

**1. Presentations planned dissemination****Presentations:**

Presentations have been made of the toolkit and development stages of the project.

# DEVELOPMENT OF A SELF-REPORTING EVALUATION TOOL FOR NEW ZEALAND GROUP-BASED SELF-MANAGEMENT EDUCATION FOR PATIENTS WITH TYPE 2 DIABETES

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## BACKGROUND AND OBJECTIVE

For most patients with Type 2 diabetes (T2DM), marked behaviour change is necessary before recommended lifestyle patterns are achieved. Making the necessary lifestyle modifications is notoriously difficult for many. We aim to develop and trial an evidence based, New Zealand (NZ) focused diabetes self-management education (DSME) programme for people with T2DM that can be delivered to groups in different settings. Evaluation of the effectiveness of the group-based DSME programme will include a qualitative assessment tool that has been tailored to the NZ setting.

## METHODS

•Obtained permission from the American Association of Diabetes Educators (AADE) to use the framework of their qualitative assessment tool D-Smart (Diabetes Self-Management Assessment Report Tool)

### WHY D-SMART?

- Widely tested in the USA to achieve high validity and reliability of all questions<sup>1</sup>
- Specific to Type 2 diabetes
- Could modify questions to fit the NZ population
  - Other popular health surveys such as SF-36 required use of exact wording<sup>3,4</sup>

## PROCESS

•Reviewed individual questions of evaluation tool for ability to accurately assess desired outcomes of:

- LIFESTYLE:** dietary intake, physical activity, medication, medication adherence including self monitoring of blood glucose, and smoking status
- PSYCHOSOCIAL OUTCOMES:** well-being, anxiety, depression, attitude, knowledge towards diabetes and empowerment

•Modified wording of select questions to fit NZ population

•Shortened the evaluation tool and re-formatted to increase ease of administration

- Split tool into 3 separate questionnaires
  - (1) Baseline
  - (2) Follow up
  - (3) Blood glucose monitoring

•Diabetes nurses pilot tested among representatives from Māori, Pacific, New Zealand European and other ethnic groups (N= 8)

•Modified based on pilot testing feedback and desirability of responses

## RESULTS

•Creation of 3 evaluation tools that will be used during the pilot testing of the group-based self-management education programme

•Questionnaires will be completed at baseline, as well as at 3 and 9 months after the DSME to assess to what degree self-management behaviours are adopted and sustained by participants.

•Survey takes approximately 10-15 minutes to complete, however length of time may differ based on participant's level of English (ie. if translation is required) or unfamiliarity of medical terminology

## CONCLUSIONS

•The evaluation tool has yet to be used throughout the programme pilot testing

•Pilot will start July 2009

•Anticipated outcomes include effective evaluation of the behaviour changes in the programme participants and the overall effectiveness of the pilot programme.

## NEXT STEPS

•Based on the pilot programme, the evaluation tool will be:

•Modified as required.

•Administered to 100 participants in October 2009 in Wellington and Dunedin.

## DEVELOPED WITH THE SUPPORT OF:

Health Research Council of New Zealand, Capital and Coast District Health Board, University of Otago, Compass Health, Diabetes New Zealand, PHOs of the Greater Wellington and Otago Regions, Base Two

## REFERENCES

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Presented by Irene Hayward at NZSSD meeting 2010.

# NEW ZEALAND GROUP-BASED SELF-MANAGEMENT EDUCATION FOR PATIENTS WITH TYPE 2 DIABETES

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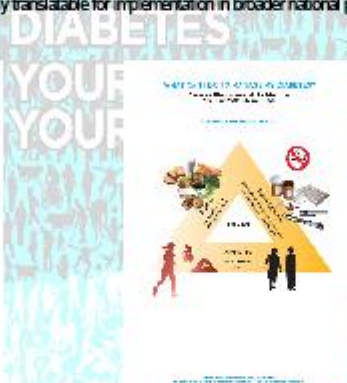
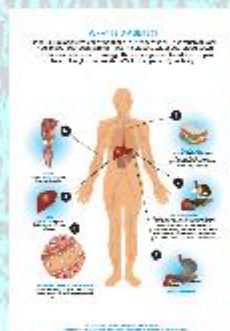
<sup>1</sup>Capital and Coast District Health Board, <sup>2</sup>Edgar National Centre for Diabetes Research, University of Otago, <sup>3</sup>University of Otago, <sup>4</sup>Compass Health Wellington Trust, <sup>5</sup>Capital FHO, <sup>6</sup>Ngati Tama Kite Upoko O te Ika, <sup>7</sup>Wellington Regional Diabetes Trust, <sup>8</sup>Simon Fraser University, Canada

## BACKGROUND AND OBJECTIVE

This study aims to develop and trial an evidence based, New Zealand focused diabetes self-management education (DSME) programme for people with Type 2 diabetes (T2DM) that can be delivered to groups in different settings.

## METHODS

The programme has been developed by translating existing international knowledge into the New Zealand context. Specifically, the programme will be flexible enough to be utilised in the wider community setting, but also tailored for specific groups within the population. As such, the findings of the research will be directly and immediately translatable for implementation in broader national primary care services.



The main outcome measures include:

- **CLINICAL MEASURES:** HbA1c, lipids, blood pressure, anthropometry
- **LIFESTYLE:** dietary intake, physical activity, medication, medication adherence including self monitoring of blood glucose, and smoking status
- **PSYCHOSOCIAL OUTCOMES:** well-being, anxiety, depression, attitude, knowledge towards diabetes and empowerment

The lifestyle factors and psychosocial outcomes will be gathered using a validated qualitative assessment tool that has been developed for the New Zealand setting using existing validated qualitative assessment instruments and pilot tested to meet the specific requirements of this study and the study population.

- *More detail can be seen in the poster presentation titled 'Development of a self-reporting evaluation tool for New Zealand group-based self-management education for patients with type 2 diabetes'.*

## THE STUDY HAS TWO STAGES

- STAGE 1:** Develop and pilot the toolkits, with specific components for Māori and Pacific peoples.
- STAGE 2:** Longitudinal trial of the programme in primary care environments.

## STAGE 1 IS CURRENTLY UNDERWAY

The concept of the programme was focus tested with practice nurses in the Wellington area and two end user groups.

One Māori and two Pacific Island group focus groups were run to discuss the programme and gather feedback on the proposed programme outline and several resources within the toolkit were shown and feedback was gathered.

The focus groups for Māori and Pacific Island people were run to ensure the toolkit meet the needs of the communities greatest affected by Type 2 diabetes.

Based on feedback from the focus groups, the toolkit was developed and will be piloted in early July.

The toolkits consist of:

- Facilitator and participant manuals
- Participant resources

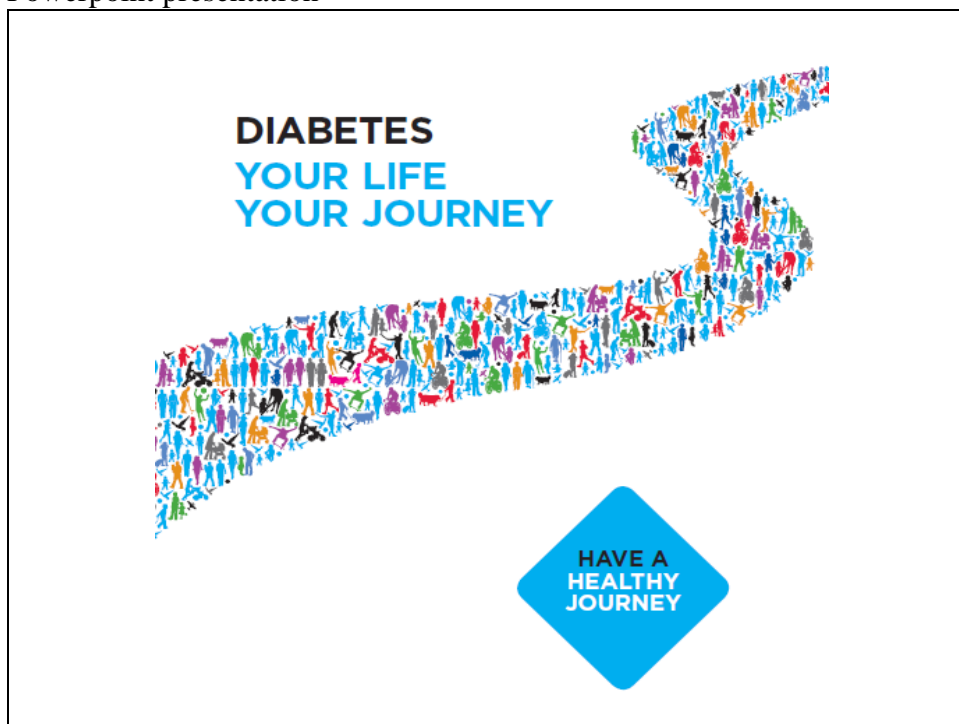
These resources build on existing handouts already in use by diabetes nurses, practice nurses as well as dietitians.

This includes three levels of information, from basic pictorial information to a combination of depth written and pictorial information.

## DEVELOPED WITH THE SUPPORT OF:

Health Research Council of New Zealand, Capital and Coast District Health Board, University of Otago, Compass Health, Diabetes New Zealand, FHOs of the Greater Wellington and Otago Regions, Base Two

- Presented at NZSSD 2010 by Eirean Gamble



- Presented at NZDA 2010 by Eirean Gamble

**Publications:**

Once the final analysis has been completed a paper will be prepared for publication. This will present the primary and secondary outcomes and will include a discussion on the challenges in conducting this research and the ability to translate evidence from this study into everyday practice.

**Implementation:**

There has already been considerable interest in the uptake and utilisation of the “Diabetes your life your journey” programme. An implementation plan has been established to provide interested parties with detailed material for facilitators, participant manuals and a list of the supplementary components of the toolkit.

Despite the lack of outcome data, on the basis of the participant feedback during phase 2 of this project, Capital PHO in Wellington and the diabetes service in the Wairarapa have already begun a roll out of the programme with at least one group having been run in each centre after the study completion.

Once the results of the study are available, they will be further disseminated through presentation at national and international diabetes meetings and primary care meetings. Results will also be made available to DHB planning and funding groups and the toolkit manuals will be made available to any interested parties.