

# **HISTORY OF DIABETES PREVENTION IN THE GREATER GREEN TRIANGLE AND THE DIABETES PREVENTION PROJECT – TELEPHONE SUPPORT FOLLOW-UP STUDY**

## **REPORT FOR UEBERGANG FOUNDATION APRIL 2009**

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## **THE HISTORY OF GREATER GREEN TRIANGLE DIABETES PREVENTION PROGRAM**

**2004-2006** National Demonstrator Diabetes Prevention Program (GGT DPP) established by Dr Laatikainen and Dr Heistaro from the National Public Health Institute of Finland.

**2007** Council of Australian Governments recognises that GGT DPP is the only evidence-based intervention for prevention of diabetes in Australia.

**2007** GGT DPP forms the basis of the Victorian Government's diabetes prevention program called *Life! Taking action on diabetes*. This program is funded for four years and aims to reduce the risk of diabetes in 25,000 Victorians.

**2007-present** Ongoing involvement of GGT UDRH staff in evaluation, development and training of group facilitators in the *Life!* program.

**2007-2008** Results of GGT DPP used to inform the Commonwealth Government's diabetes prevention program leading to new Medicare item numbers for diabetes prevention.

**2007** Visit by Finnish team from their diabetes prevention program with Finnish uptake of the training program developed in GGT UDRH.

**2008** Presentation of results GGT DPP at World Congress for Diabetes Prevention in Helsinki, Finland.

**2008** GGT DPP chosen from all programs worldwide for adoption as a diabetes prevention program for southwest England.

**2008** Award of \$834,000 research grant by National Health and Medical Research Council to study the effectiveness and cost effectiveness of the Victorian *Life!* Program.

**2009** Visit by academics and health professionals from southwest England to undergo training in diabetes prevention.

**2009** Commonwealth Department of Health and Ageing offers to fund a further follow-up study. A proposal building on the results of the study funded by Uebergang Foundation is currently with the Department.

# Diabetes Prevention Project – Telephone Support Follow-Up Study: Final report

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### ***Executive summary***

Type 2 Diabetes Mellitus is a major current health issues in modern society. In Australia, the prevalence of diabetes is on the rise as are the associated health problems and health care costs..

In 2004-2006, the Greater Green Triangle University Department of Rural Health (GGT UDRH) developed a Diabetes Prevention Program (GGT DPP) for use in Australian primary health care settings with English speaking groups. This GGT DPP was based on the Finnish Diabetes Prevention Study (DPS) and the Good Ageing in Lahti Region (GOAL) Lifestyle Implementation Trial. The overall result of the GGT DPP was a 40% risk reduction for Type 2 Diabetes Mellitus.

With the success of the intervention program, GGT UDRH undertook an evaluation of the sustainability of the lifestyle changes implemented during the initial 12 months. This second part of the study also tested whether regular structured telephone calls could be effective in maintaining lifestyle changes by providing support to participants.

The research findings show that positive outcomes at 12 months were generally maintained after a further 18 months for those who received regular structured telephone calls as well as those who were in the control group (i.e. no telephone calls). The study has contributed to a better understanding of factors that contribute to successful lifestyle change among participants in the diabetes prevention program. This information has contributed to research ideas that have led to further applications for research funding. We have received our first National Health and Medical Research Council grant and have three other applications with the NHMRC for their consideration.

## ***Background***

Type 2 Diabetes Mellitus (T2DM) is recognized as a major current health issue in modern society.<sup>1, 2</sup> The risk of developing T2DM is about equally attributable to the environmental and genetic factors,<sup>1</sup> but the recent increase in incidence is mainly due to lifestyle factors. In 2004-2005, about 700,000 Australians, or 3.6% of the population,<sup>3</sup> had been diagnosed with diabetes. About half of those who have diabetes are not aware of their condition, so the problem may be more serious than what is known from survey data. Of those with diabetes, around 13% have type 1 (insulin-dependent) and 83% have type 2 (non-insulin dependent) diabetes (4% type unknown).<sup>3</sup> It is estimated that about two million Australians may have pre-diabetes or impaired glucose tolerance, which is an early indicator for developing diabetes (about one in three will go on to develop type 2 diabetes).

In 2004-2006, the Greater Green Triangle University Department of Rural Health (GGT UDRH) developed a Diabetes Prevention Program (GGT DPP) for use in Australian primary health care settings in English speaking groups.<sup>4</sup> This GGT DPP was based on the Finnish Diabetes Prevention Study (DPS)<sup>5</sup> and the Good Ageing in Lahti Region (GOAL) Lifestyle Implementation Trial.<sup>6</sup> Both of these interventions used a lifestyle behaviour change approach in primary health care settings for those at high risk. The intervention goals for both studies were:

1. No more than 30% energy from fat
2. No more than 10% energy from saturated fat
3. At least 15g/1000 kcal fiber
4. 30 min/day moderate intensity physical activity
5. 5% reduction in body weight

The Finnish DPS showed a relative risk reduction of 58% after a mean intervention period of three years. This result has been sustained during the three years follow-up after intervention with a 43% relative risk reduction for T2DM.<sup>7</sup> Similar results using the same approach were obtained in the GGT

DPP. These included a mean weight reduction of 2.52 kg and waist circumference by 4.17 cm, and a risk reduction for T2DM of 40%. The study provided evidence that a type 2 diabetes prevention program using lifestyle intervention is feasible in primary health care settings in Australia.<sup>4</sup>

Components of an ideal ongoing program to sustain lifestyle changes achieved are yet to be determined. Recent studies evaluating use of the telephone as a primary method for delivering lifestyle and chronic disease management interventions have shown promising results. The telephone has considerable potential: it is relatively inexpensive, widely available, not limited by geographical barriers, and is being increasingly adopted by large government and non-government organisations to deliver large-scale interventions.

To the best of our knowledge, this is the first follow-up study of participants in a diabetes prevention program conducted in the real world settings of the health service, rather than the highly resourced circumstances of a clinical trial.

### ***Working hypotheses***

The hypotheses in this study were:

- 1) that gains achieved at 12 months would be sustained at 30 months,  
and
- 2) that continuing telephone support with group facilitators would result in better maintenance of outcomes 18 months after completing the original 12 month GGT DPP intervention.

## ***Design and methods***

### *Design, recruitment and main intervention*

The GGT DPP was conducted in Victoria and South Australia in 2004–2006 using primary health care as a setting to reduce the incidence of T2DM.<sup>4</sup> The Finnish Diabetes Risk Score (FINDRISC) tool<sup>8</sup> was used in general practices from three regions to identify patients at high risk of developing T2DM. On this scale, scores range from 0 to 26. A score of  $\geq 12$  predicts development of T2DM in more than one in six individuals within 10 years. A minimum score of 12 was the main criterion for recruitment. The intervention model used in this study, described in detail elsewhere,<sup>4</sup> was based on the Finnish GOAL study.<sup>9</sup> The program consisted of six two-hour group sessions, the first five over eight weeks and the last delivered at eight months. A goal setting and planning approach was used to enhance behaviour change in physical activity and dietary habits. Regular self-assessment was used to empower participants to make personal short and long term goals and create structured plans to achieve these. As in the Finnish study,<sup>10</sup> five goals were targeted with these aims: 1) less than 30 percent of total energy intake from fat; 2) less than 10 percent of total energy intake from saturated fat; 3) more than 15g of fibre/1,000 calories; 4) more than 4 hours/week of moderate level physical activity; and 5) more than 5 percent weight reduction.

In total, 311 participants (88 men and 223 women) aged 40–75 years were eligible to participate, and 237 of these attended both baseline and 12 month health checks and at least one of the six sessions of the program (Figure 1).

### *Randomisation*

According to facilitator records, 228 individuals were expected to complete the GGT DPP and be willing to participate in the follow-up. They were randomised into a group receiving telephone support and a group without telephone support (self care), stratified by session group, with 11 married couples kept

together to limit contamination. Seventeen participants not completing the GGT DPP and four previously diagnosed with T2DM were excluded. Another two who attended sessions but were outside the age limit set in the GGT DPP were also excluded. The remaining 205 were allocated to telephone support (n=107) and self care only (n=98).

#### *Telephone support follow-up*

The telephone support group received regular calls from specially trained nurses, mainly recruited from the original GGT DPP,<sup>4</sup> supervised by a clinical health psychologist with experience in chronic disease management and T2DM intervention programs. Calls followed a semi-structured questionnaire. This contained the personal goals (physical activity and diet) that had been set at the end of the 12 month intervention, and specific questions on achievement, compliance, and difficulties encountered. Nurses recorded this information and gave advice and encouragement towards achieving and maintaining these goals. If necessary support materials were sent to participants, or they were referred to a relevant support service when stress, anxiety or depression issues were detected. Participants were phoned 4 weeks after completing the initial 12 months GGT DPP, monthly for the next five months, and bi-monthly for the subsequent 12 months (maximum of 12 phone calls). Calls lasted approximately 15 minutes, depending on support required. The self-care groups were not contacted by study nurses during the follow-up until being invited to attend the 30 month clinical tests.

#### *Measurements*

Clinical measurements including height, weight, waist and hip circumference, and blood pressure measurements, were made by study nurses at the end of the 12 month main intervention as previously described<sup>4</sup> and the end of the 30 months. Participants fasted overnight for a minimum of eight hours. Fasting plasma glucose, 2 hour oral glucose tolerance test (2hr-OGTT), total

cholesterol, triglycerides and high density lipoprotein (HDL) cholesterol were analysed.<sup>4</sup> Use of lipid and blood pressure lowering medication was also recorded.

In addition, participants were assessed for psychological distress (Kessler 10 Psychological Distress Scale),<sup>11</sup> anxiety and depression (Hospital Anxiety and Depression Scale (HADS)).<sup>12</sup> General health was assessed using the Short Form 36 (SF-36v2)<sup>13</sup> standardised to Australian population norms.<sup>14</sup>

### *Ethics*

Participants gave written consent. The study was approved by the Flinders University Clinical Research Ethics Committee (reference number 105/034) and registered as a clinical trial (ISRCTN38031372).

### **Results**

Of 205 eligible participants, 144 completed the follow-up. Of these, 66 received telephone support (mean 7.5 calls, SD 1.4, mean length of call 20 minutes) and 78 had self-care information only (Figure 1).

The self-care group had more men than the telephone support group (35% versus 15%,  $p=0.013$ ) but otherwise the groups were well matched (Table 1).

Changes in telephone support and self care groups were minimal and similar between 12 and 30 months (Table 2). Hence a global analysis including an additional 24 participants who had complete information (16 telephone support participants who did not receive any calls, 4 who developed T2DM during the original 12 month intervention, and 4 not included in the sample) was undertaken in order to assess the longer term effect of the GGT DPP.

In the 168 participants who completed the 30 month study (12 month DPP intervention and 18 month follow-up), improvements in anthropometric, blood

pressure, and lipid variables apparent at 12 months were generally maintained at 30 months with some exceptions (Table 3).

**Although weight** increased by 1.04 kg during the follow-up period (12-30 months) there was still **a 30 month mean reduction of 1.65 kg. Waist circumference** decreased further during the follow-up and after 30 months there was a **mean reduction of 4.09 cm**. Decrease in **2hr-OGTT** during the first 12 months attenuated during follow-up, but at **30 months was still significantly better** (0.37 mmol/L) than baseline. In contrast, fasting plasma glucose, which improved during the original 12 month study, increased during follow-up, and was 0.23 mmol/L higher at 30 months than baseline.

**Triglycerides and total cholesterol showed further improvement.** This resulted in **overall reductions of 0.32 and 0.41 mmol/L** respectively.

After commencement of the initial 12 month intervention, 12 participants started medication for dyslipidemia (n=5 during the GGT DPP and n=7 during the follow-up) and 10 for hypertension (n=2 during the GGT DPP and n=8 during the follow-up). When these are excluded, there is a slight increase in systolic blood pressure during follow-up. Also reduction in total cholesterol during follow-up was no longer evident.

The impact on psychological measures was mixed. Depression scores improved during the initial 12 month intervention but subsequently regressed to baseline. Also the statistically significant effect on psychological distress diminished during follow-up so that at the end the effect was no longer statistically significant. Positive effects observed on bodily pain, general health and vitality were maintained during follow-up. Mental health and physical composite scores regressed toward baseline. Anxiety scores and all other measures of health were unchanged.

## ***Discussion***

The present study suggests that gains achieved during the GGT DPP<sup>4</sup> can be sustained over the following 18 months.

The success of the main intervention relied on the theories of behaviour change that were used. The theoretical framework of this intervention was based on the Health Action Process Approach (HAPA) (ref) and on self-regulation theory (ref). The HAPA model incorporates a two-stage model with distinct phases for motivation formation and action. During the first phase, the participant reaches a point where he/she is considering the possibility of change. Here, risk perception, motives, self-efficacy in decision-making, and outcome expectations contribute to goal intentions. Planning short-term objectives is an important element in the model, bridging the two phases. During the second stage or action phase, implementation intentions help participants to start working towards their goals. Crucial elements are self-efficacy, skills for overcoming barriers and making use of resources.

Alongside the HAPA model, self-regulation theory helps participants formulate goals and find strategies to achieve these goals through the difficult process of planning preparation and initiation of intended behaviour change action (ref). The formulation of distinct goal intentions offers a way to overcome the gap between intention and behaviour.

Participants involved in the 12 month intervention were guided to plan how they would start achieving their behaviour changes. They incorporated the basic principles and appropriate skills into daily life in order to choose and plan concrete, positive, attainable and evolving goals that can also be sustained and achieved in the long term. Participants set personal goals such as 'eat more fruit and vegetables', 'have healthier snacks ready' or 'walk around the block with the dog'.

When participants agreed to continue our study with 18 month telephone support follow up, they were able to:

- acknowledge that they were at risk for type 2 diabetes,
- learn that the disease can be prevented by lifestyle changes,
- gain confidence in their ability to change,
- decide to change,
- plan where, when and how to make changes,
- learn how to avoid barriers and use resources,
- learn how to recover from relapses.

Prevention programs demonstrate substantial benefits of healthy lifestyle changes in reducing risk of developing T2DM.<sup>10, 15-17</sup> The GGT DPP lifestyle intervention study achieved results comparable with earlier clinical trials.<sup>15, 17, 18</sup> For successful chronic disease programs, sustained effects are of major interest. Some weight loss and smoking cessation programs have shown loss of benefits in the long term, such as regaining weight, sometimes higher<sup>19</sup> than the initial weight, or reversion to smoking.<sup>20</sup> By comparison, clinical trials of diabetes prevention programs seem to have been particularly successful in sustaining effects.<sup>7, 21</sup>

As an extension of the GGT DPP, **telephone counseling aimed to support participants in sustaining the benefits already achieved, rather than to facilitate further improvement.**

In the present study, outcomes of particular interest included physical (weight, waist and hip circumference, and blood pressure) and biochemical (total, LDL- and HDL-cholesterol, triglycerides, fasting plasma glucose and 2hr-OGTT) measurements at 30 months. Almost all improvements shown at 12 months were sustained at 30 months with the main exception of fasting plasma glucose. Weight rebounded during follow-up, however reduction in waist circumference was maintained. This is of major importance because central adiposity is the main driver of metabolic abnormalities that lead to type 2

diabetes.<sup>22</sup> Improvements in diastolic blood pressure and lipids, especially triglycerides were maintained.

During telephone support calls, enablers and barriers were discussed with participants, and actions taken such as referral to GP or counsellor when needed. In general, the nurses reported a lack of new issues to discuss with participants. Although 12 telephone calls were scheduled, participants received an average of 7.5 calls. Length of calls decreased over time, and participants who received more calls tended to have worse mental health and cholesterol, and better physical functioning. Telephone support could not have alleviated physical problems, and it is likely that those who had already been successful in their lifestyle changes did not find much benefit in support. Others may have struggled with meeting their goals and accepted more calls, but required more than was offered by the telephone support. The social support offered by the telephone calls may have also been a substitute for support obtained in group sessions.

No significant differences in mean outcome measures were found between the groups with and without telephone support. There was a small positive effect in terms of waist circumference and depression. Also, participants with telephone support more often tended to maintain waist circumference (48% vs 32%,  $p=0.098$ ) and LDL-cholesterol (49% vs 25%,  $p=0.023$ ), but tended to be less likely to maintain anxiety improvements (35% vs 61%, 0.054).

Email was considered as an alternative to telephone communication. However, this appeared less appropriate with an older age group from a rural area with poor access to the internet, and preference for more personalised verbal communication. Also the telephone has considerable potential: it is relatively inexpensive, widely available, not limited by geographical barriers, and is being increasingly adopted by large government and non-government organisations to deliver large-scale interventions. Despite advantages of telephone support, studies reporting its use in diabetes management have not

demonstrated effectiveness for sustaining lifestyle changes post-intervention.<sup>23</sup>

The major strength of this study is that it has been successfully implemented within a primary care setting and is the first to report sustainability of a group based diabetes prevention program over 18 months of follow-up. There were some dropouts. Also, in a small community, the likelihood of cross-contamination is increased, and we have no information regarding further contact between participants.

A limitation of this study is that we have not been able to clearly demonstrate whether telephone support following group-based diabetes prevention is effective. This was probably due to the small number of participants studied, and may have resulted in the effect not being detected. Within GGT DPP, participants had already achieved their behaviour change goals and the necessary skills to maintain them during the first 3 months of the initial intervention. Addition of telephone support may have had no measurable further impact. Support gained through group interaction during the 12 month GGT DPP appears to have had the greatest impact as initial achievements at 3 months were sustained at 12 months.<sup>4</sup> Absence of group social interaction may have led participants to lose motivation. Whilst evidence supporting efficacy of the telephone as a primary intervention method to deliver physical activity and dietary behaviour change intervention is promising, effects on outcomes measured have been mainly short-term with very few significant reductions reported for body mass index (BMI), lipids or blood pressure.<sup>24</sup>

### **Conclusion**

Providing telephone support on completion of the initial 12 month intervention did not appear to produce additional benefits at 30 months. Homogeneity between follow-up groups has provided the opportunity to demonstrate that sustained benefits observed in the DPS can be similarly reproduced in a

primary care setting. In conclusion, we have shown that this group based prevention program in a primary health care setting for individuals at high risk of T2DM, results in good initial outcomes which are sustained at 30 months.

Work is now under way to understand better which participants are best able to maintain the benefits of the program in the longer run. Lessons learnt can be incorporated into facilitator training so that we can enable future participants to benefit fully.

### ***Acknowledgements***

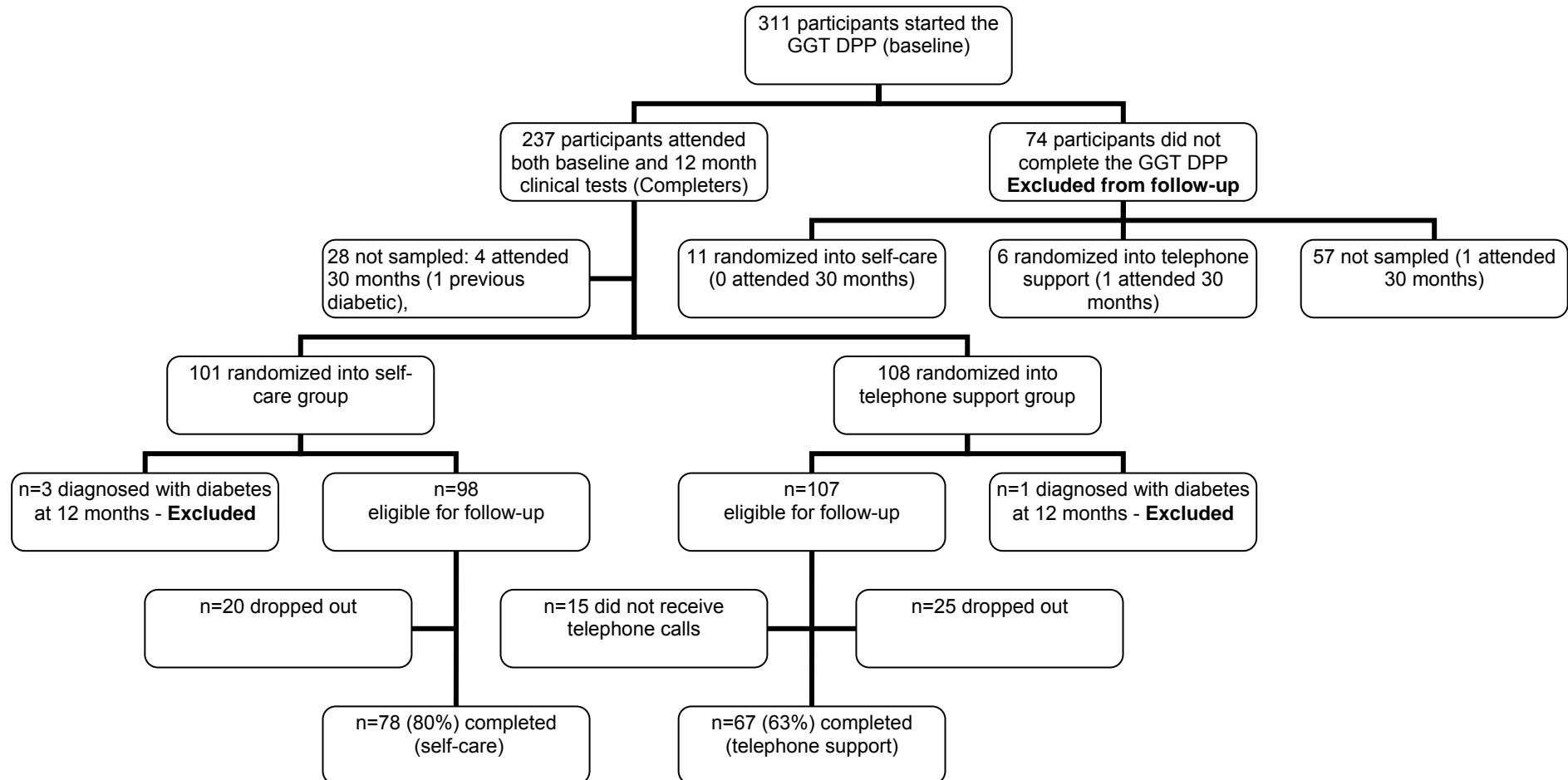
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Figure 1. Participants in the study



**Table 1.** Mean (SE) difference between self-care participants (n=78) and telephone support participants (n=67) at baseline (demographics) and 12 months (anthropometric & psychosocial)

	Self-care	Telephone support	Difference	p-value
	n=78	n=66		
<b><u>Baseline</u></b>				
Gender (% male)	n=27 (34.6%)	n=10 (15.2%)	19.46%	0.013
Age (years)	56.5 (0.9)	56.6 (1.1)	-0.14 (1.46)	0.926
Education (years)	12.2 (0.4)	11.9 (0.5)	0.33 (0.57)	0.566
<b><u>Beginning of Telephone Support</u></b>				
Systolic Blood Pressure (mmHg)	130.8 (1.7)	130.4 (2.1)	0.44 (2.69)	0.872
Diastolic Blood Pressure (mmHg)	79.2 (1.0)	78.3 (1.2)	0.86 (1.57)	0.585
Weight (kg)	89.9 (2.2)	87.5 (2.0)	2.35 (3.03)	0.440
BMI (kg/m <sup>2</sup> )	32.1 (0.6)	32.5 (0.8)	-0.32 (0.98)	0.749
Waist Circumference (cm)	100.3 (1.7)	99.6 (1.4)	0.66 (2.22)	0.766
Hip Circumference (cm)	111.9 (1.5)	113.8 (1.6)	-1.95 (2.15)	0.366
2hr-OGTT (mmol/L)	6.03 (0.18)	5.92 (0.19)	0.11 (0.26)	0.683
Fasting Plasma Glucose (mmol/L)	5.37 (0.06)	5.23 (0.07)	0.13 (0.09)	0.136
Total Cholesterol (mmol/L)	5.42 (0.13)	5.31 (0.12)	0.11 (0.18)	0.542
Triglycerides (mmol/L)	1.85 (0.11)	1.75 (0.15)	0.10 (0.18)	0.587
HDL-cholesterol (mmol/L)	1.38 (0.04)	1.47 (0.05)	-0.09 (0.07)	0.174
LDL-cholesterol (mmol/L)	3.22 (0.12)	3.06 (0.11)	0.16 (0.17)	0.337
K-10 Score	14.6 (0.8)	14.6 (0.5)	0.06 (0.98)	0.948
HADS Anxiety Score	3.17 (0.39)	3.14 (0.32)	0.03 (0.52)	0.957
HADS Depression Score	2.23 (0.36)	2.43 (0.32)	-0.20 (0.49)	0.687
<i>SF-36 v2</i>				
Physical Functioning	49.0 (1.0)	48.4 (1.1)	0.60 (1.52)	0.692
Role Limitations Physical	48.4 (1.1)	47.9 (1.1)	0.43 (1.55)	0.780
Bodily Pain	46.9 (1.3)	46.0 (1.4)	0.97 (1.88)	0.608
General Health	50.5 (0.9)	50.3 (0.8)	0.21 (1.25)	0.870
Vitality	51.0 (1.0)	49.9 (1.0)	1.16 (1.39)	0.408
Social Functioning	48.4 (1.2)	48.4 (1.1)	-0.07 (1.67)	0.966
Role Limitation Emotional	46.1 (1.5)	46.4 (1.4)	-0.31 (2.08)	0.883
Mental Health	49.4 (1.1)	47.6 (1.1)	1.74 (1.59)	0.276
Physical Composite Score	49.1 (1.0)	48.7 (1.1)	0.34 (1.47)	0.817
Mental Composite Score	48.5 (1.3)	47.7 (1.2)	0.84 (1.81)	0.644

**Table 2.** Mean (SE) changes in self-care and telephone support groups from 12 months to 30 months

	<b>Self-care</b>	<b>Telephone support</b>	<b>Difference</b>	<b>p-value</b>
	n=78	n=66		
Systolic Blood Pressure (mmHg)	2.25 (1.73)	1.20 (1.80)	1.05 (2.50)	0.136
Diastolic Blood Pressure (mmHg)	-0.03 (1.31)	0.08 (1.03)	-0.10 (1.72)	0.525
Weight (kg)	1.12 (0.53)	1.10 (0.59)	0.02 (0.79)	0.954
BMI (kg/m <sup>2</sup> )	0.43 (0.19)	0.39 (0.23)	0.03 (0.30)	0.909
Waist Circumference (cm)	0.32 (0.60)	-0.88 (0.74)	1.20 (0.94)	0.443
Hip Circumference (cm)	0.64 (0.52)	0.70 (0.57)	-0.06 (0.77)	0.801
2hr-OGTT (mmol/L)	0.13 (0.22)	-0.02 (0.21)	0.15 (0.31)	0.598
Fasting Plasma Glucose (mmol/L)	0.38 (0.05)	0.38 (0.05)	0.00 (0.07)	0.394
Total Cholesterol (mmol/L)	-0.22 (0.12)	-0.19 (0.11)	-0.03 (0.16)	0.507
Triglycerides (mmol/L)	-0.17 (0.09)	-0.25 (0.07)	0.07 (0.11)	0.318
HDL-cholesterol (mmol/L)	0.00 (0.02)	-0.03 (0.03)	0.03 (0.04)	0.609
LDL-cholesterol (mmol/L)	-0.11 (0.11)	-0.04 (0.09)	-0.07 (0.15)	0.687
K-10 Score	0.10 (0.47)	0.00 (0.63)	0.10 (0.78)	0.770
HADS Anxiety Score	0.46 (0.38)	0.48 (0.45)	-0.02 (0.59)	0.376
HADS Depression Score	0.65 (0.30)	0.13 (0.32)	0.52 (0.44)	0.124
<i>SF-36 v2</i>				
Physical Functioning	-1.37 (0.82)	-0.38 (0.75)	-0.98 (1.13)	0.458
Role Limitations Physical	-0.23 (1.00)	0.00 (0.95)	-0.23 (1.39)	0.911
Bodily Pain	-1.26 (1.03)	-0.92 (1.15)	-0.34 (1.54)	0.874
General Health	-1.29 (0.64)	-0.66 (0.73)	-0.63 (0.97)	0.701
Vitality	-1.10 (0.81)	-0.80 (1.02)	-0.29 (1.29)	0.687
Social Functioning	0.67 (1.21)	-0.95 (1.29)	1.62 (1.77)	0.313
Role Limitations Emotional	0.06 (1.44)	-0.95 (1.38)	1.02 (2.01)	0.732
Mental Health	-0.28 (1.06)	0.41 (1.24)	-0.69 (1.62)	0.551
Physical Composite Score	-1.31 (0.90)	-0.51 (0.80)	-0.80 (1.22)	0.623
Mental Composite Score	0.32 (1.25)	-0.43 (1.38)	0.74 (1.85)	0.822

**Table 3.** Comparison of means (SE) at baseline, 12 months and 30 months and mean changes (95% CI) between baseline and 12 months, 12 months and 30 months and baseline and 30 months

	<b>0 months</b>	<b>12 months</b>	<b>30 months</b>	<b>Changes 0-12</b>	<b>Changes 12-30</b>	<b>Changes 0-30</b>
Systolic Blood Pressure (mmHg)	131.4 (1.3)	130.5 (1.2)	132.2 (1.2)	-0.95 (-2.94,1.05)	1.66 (-0.58,3.91)	0.72 (-1.68,3.12)
Diastolic Blood Pressure (mmHg)	80.7 (0.8)	78.6 (0.7)	78.8 (0.8)	-2.15 (-3.61,-0.69)	0.18 (-1.36,1.72)	-1.97 (-3.53,-0.41)
Weight (kg)	92.0 (1.4)	89.3 (1.4)	90.3 (1.4)	-2.69 (-3.53,-1.85)	1.04 (0.33,1.74)	-1.65 (-2.52,-0.79)
BMI (kg/m <sup>2</sup> )	33.4 (0.5)	32.4 (0.5)	32.8 (0.5)	-0.98 (-1.29,-0.68)	0.38 (0.12,0.65)	-0.60 (-0.92,-0.28)
Waist Circumference (cm)	104.5 (1.0)	100.6 (1.0)	100.4 (1.1)	-3.92 (-4.71,-3.13)	-0.17 (-1.02,0.68)	-4.09 (-5.01,-3.17)
Hip Circumference (cm)	115.4 (1.0)	112.8 (1.0)	113.4 (1.0)	-2.57 (-3.26,-1.89)	0.62 (-0.08,1.32)	-1.95 (-2.75,-1.15)
2hr-OGTT	6.68 (0.13)	6.02 (0.13)	6.30 (0.17)	-0.65 (-0.91,-0.40)	0.28 (0.00,0.56)	-0.37 (-0.68,-0.07)
Fasting Plasma Glucose	5.52 (0.04)	5.36 (0.05)	5.75 (0.05)	-0.16 (-0.23,-0.08)	0.39 (0.32,0.46)	0.23 (0.16,0.30)
Total Cholesterol	5.63 (0.08)	5.40 (0.08)	5.22 (0.08)	-0.23 (-0.36,-0.11)	-0.18 (-0.32,-0.03)	-0.41 (-0.56,-0.26)
Triglycerides	1.96 (0.08)	1.81 (0.08)	1.63 (0.08)	-0.14 (-0.26,-0.03)	-0.18 (-0.29,-0.07)	-0.32 (-0.45,-0.20)
HDL-cholesterol	1.35 (0.03)	1.42 (0.03)	1.40 (0.03)	0.08 (0.04,0.11)	-0.03 (-0.06,0.01)	0.05 (0.02,0.08)
LDL-cholesterol	3.40 (0.08)	3.17 (0.08)	3.12 (0.07)	-0.23 (-0.34,-0.12)	-0.05 (-0.18,0.08)	-0.28 (-0.41,-0.16)
K-10 Score	15.0 (0.4)	14.3 (0.4)	14.4 (0.5)	-0.76 (-1.36,-0.15)	0.10 (-0.63,0.82)	-0.66 (-1.41,0.08)
HADS Anxiety Score	3.35 (0.24)	3.08 (0.24)	3.50 (0.30)	-0.27 (-0.72,0.19)	0.41 (-0.11,0.93)	0.15 (-0.39,0.68)
HADS Depression Score	2.84 (0.23)	2.35 (0.23)	2.78 (0.25)	-0.49 (-0.88,-0.10)	0.43 (0.03,0.83)	-0.06 (-0.44,0.32)
<i>SF-36 v2</i>						
Physical Functioning	47.9 (0.6)	48.7 (0.7)	48.0 (0.7)	0.86 (-0.21,1.93)	-0.71 (-1.72,0.29)	0.15 (-1.02,1.31)
Role Limitations Physical	47.6 (0.7)	47.9 (0.7)	47.9 (0.7)	0.35 (-1.08,1.77)	-0.02 (-1.27,1.24)	0.33 (-1.18,1.84)
Bodily Pain	43.3 (0.9)	46.3 (0.9)	45.4 (0.9)	2.93 (1.25,4.60)	-0.90 (-2.32,0.52)	2.02 (0.29,3.76)
General Health	47.6 (0.6)	50.2 (0.6)	49.5 (0.6)	2.60 (1.61,3.60)	-0.68 (-1.54,0.18)	1.92 (0.89,2.95)
Vitality	47.6 (0.7)	50.7 (0.6)	49.7 (0.7)	3.07 (1.89,4.24)	-0.99 (-2.17,0.19)	2.08 (0.75,3.41)
Social Functioning	49.0 (0.7)	48.6 (0.8)	48.4 (0.8)	-0.41 (-1.89,1.06)	-0.24 (-1.76,1.28)	-0.65 (-2.05,0.75)
Role Limitations Emotional	46.7 (1.0)	46.5 (1.0)	46.0 (1.0)	-0.12 (-2.23,1.99)	-0.54 (-2.28,1.21)	-0.65 (-2.51,1.20)
Mental Health	47.0 (0.8)	49.0 (0.7)	48.5 (0.8)	1.95 (0.62,3.28)	-0.42 (-1.87,1.03)	1.53 (-0.02,3.08)
Physical Composite Score	46.9 (0.7)	48.7 (0.7)	48.0 (0.7)	1.83 (0.69,2.96)	-0.67 (-1.81,0.48)	1.16 (-0.18,2.50)
Mental Composite Score	47.4 (0.9)	48.3 (0.9)	48.0 (1.0)	0.86 (-0.73,2.46)	-0.32 (-2.00,1.37)	0.55 (-1.06,2.16)