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Management of people with Type 2 diabetes shared between a specialized outpatient clinic and primary health care is noninferior to management in a specialized outpatient clinic: a randomized, noninferiority trial*
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What’s new?

- Most studies on shared care models targeting people with Type 2 diabetes have multifaceted interventions and short follow-up periods.
- Our shared care model consisted of one annual comprehensive check-up at a specialized diabetes outpatient clinic, plus three quarterly consultations in general practice.
- We found that participants followed in the shared care programme did not have worse HbA\textsubscript{1c} outcomes compared with participants followed solely in a specialized diabetes outpatient clinic.
• Shared care pathways could be part of future diabetes management because people with Type 2 diabetes can benefit from the specialized diabetes team while keeping close contact with their general practitioner.

Abstract

Aim To evaluate whether management of people with Type 2 diabetes shared between a specialized outpatient clinic and primary health care has noninferior HbA1c outcomes compared with mono-sectorial management in a specialized outpatient clinic.

Methods A randomized controlled, noninferiority study. People with moderate hyperglycaemia, hypertension and/or incipient complications were eligible for the study. All participants had annual comprehensive check-ups at the outpatient clinic. Quarterly check-ups were conducted by general practitioners (GPs) for the shared care group and by endocrinologists at the outpatient clinic for the control group. The primary outcome was the mean difference in HbA1c from baseline to 12 months of follow-up. The noninferiority margin for HbA1c was 4.4 mmol/mol.

Results A total of 140 people were randomized [age 65.0 ± 0.9 years, HbA1c 52 ± 0.8 mmol/mol (6.9 ± 0.1%), systolic BP 135.6 ± 1.1 mmHg; all mean ± SEM]. Peripheral neuropathy was present in 68% of participants and microalbuminuria in 19%; 15% had history of a previous major cardiovascular event. Among study completers (n = 133), HbA1c increased by 2.3 mmol/mol (0.2%) in the shared care group and by 1.0 mmol/mol (0.1%) in the control group, with a between-group difference of 1.3 mmol/mol [90% confidence interval (CI) −1.3, 3.9] (0.1%, 90% CI −0.1, 0.4). Noninferiority was confirmed in both per protocol and intention to treat analyses.
**Conclusion** We found that our shared care programme was noninferior to specialized outpatient management in maintaining glycaemic control in this group of people with Type 2 diabetes. Shared care should be considered for the future diabetes management of Type 2 diabetes.

**Introduction**

The increasing prevalence of Type 2 diabetes challenges healthcare systems worldwide to provide high-quality care and to ensure optimal utilization of the available healthcare resources [1]. According to the World Health Organization (WHO), healthcare systems need to be reconfigured with innovative and integrated models of care for people with chronic diseases with the cooperation of all healthcare sectors [1,2]. One way to concretize integrated care is by adopting shared care models, which can be defined as general practitioners (GPs) and specialists sharing the delivery of care [3]. During the past decades, such shared care models have been designed and tested for people with Type 2 diabetes with the purpose of providing qualified healthcare services. Focus has been on combining the disease-specific expertise of the endocrinologist [4–9] with the GP’s knowledge of general health and everyday living [10]. In most interventions testing shared care models, the majority of consultations take place in general practice, all consultations in some models [4–6,11,12], whereas others include an annual check-up at a specialized outpatient clinic [7,8,13,14].

According to a recent Cochrane review, there is no firm consensus on the effect of shared care models for the management of chronic diseases, because the effects on physical clinical outcomes are limited or absent [10]. In studies on shared care models for people with Type 2 diabetes, the available evidence derives from an array of countries with differences in both
the structure of healthcare systems and the accessibility of services. Furthermore, there is substantial heterogeneity in the way that shared care interventions and studies are designed [10]. It is recommended that future evaluations of shared care models should be conducted as randomized controlled trials (RCTs) with well-defined interventions and long follow-up periods [10].

In guidelines from the Capital Region in Denmark, shared care is suggested as a model of care for people with moderately dysregulated Type 2 diabetes and/or incipient diabetic complications [15]. However, a Danish shared care model has not been implemented or evaluated in a randomized trial to date. In this study, we aimed to investigate if management of people with Type 2 diabetes shared between a specialized outpatient clinic and primary health care has a noninferior outcome of HbA1c compared with mono-sectorial management in a specialized outpatient clinic. The rationale of employing a noninferiority trial design was based on the expectation that noninferiority of shared care could lead eventually to more rational and cost-effective use of healthcare resources.

**Participants and methods**

**Study design**

The trial protocol has been published previously [16]. In brief, the study was a prospective, randomized trial with two groups: a shared care group and a usual care group. The study was designed as a noninferiority trial testing the hypothesis that participants following a shared care model would have no worse outcome of HbA1c compared with participants followed in a well-established outpatient clinic. The study protocol was approved by the Committees on
Health Research Ethics in the Capital Region of Denmark (H-4-2014-069) and registered with the Danish Data Protection agency (GEH-2015-085) and ClinicalTrials.gov (NCT02586545). All participants were informed orally and in writing, before giving informed consent.

**<H2>Settings**

In Denmark, all residents have tax-financed universal access to primary and secondary healthcare services. Approximately 80–90% of people with Type 2 diabetes are followed in general practice, whereas 10–20% are referred to specialized diabetes outpatient clinics at public hospitals. All Danes are registered with a GP, who acts as a gatekeeper to specialized care. Of the 150 GPs in the hospital’s service area, 29 agreed to participate in the study. Annual comprehensive check-ups were conducted at the specialized diabetes outpatient clinic at Steno Diabetes Center Copenhagen, Gentofte Hospital, University of Copenhagen. Routine check-ups were conducted at general practice or at the diabetes outpatient clinic, according to randomization.

**<H2>Participants**

The inclusion and exclusion criteria have been described in detail previously [16]. Briefly, participants had to be at risk stratification level 2 according to the Danish Risk Stratification Model [15,17]. This model divides people into three levels according to the disease severity (Fig. S1). People at level 2 are characterized by either hyperglycaemia (HbA1c 53–75 mmol/mol; 7–9%), hypertension (BP 130/80 to 160/90 mmHg) and/or incipient diabetic complications. Before being invited to take part in the study, potential participants were pre-
screened based on available medical data. Participants were only eligible if they were registered with one of the 29 participating GPs. At the time of recruitment, participants were followed for their Type 2 diabetes in either primary care or the outpatient clinic: 73 were referred from general practice and 67 were recruited from the outpatient clinic. The two groups had comparable characteristics, except for a significantly higher systolic BP among participants recruited from general practice ($P = 0.02$) (Table S1).

**Randomization and blinding**

A statistician designed the randomization sequence. A secretary in a neighbouring department prepared sealed envelopes and managed the randomization process. We randomized in a 1:1 ratio and in blocks of two (intervention : control) for each GP. Participants, healthcare professionals and researchers were blinded during the initial baseline visit. After randomization, further blinding was not possible.

**Intervention group**

The annual cycle of the shared care programme consisted of one comprehensive check-up at the outpatient clinic and three quarterly consultations with healthcare professionals in primary care [16]. The comprehensive check-up comprised laboratory tests, fundoscopy, and consultations with a diabetes nurse and an endocrinologist, respectively. The study protocol did not specify the detailed content of the consultations in primary care. GPs were encouraged to practise according to the national guidelines for Type 2 diabetes management in primary care [18]. GPs received an electronic copy of the medical report performed by the endocrinologist after the annual comprehensive check-up including: treatment targets, focus
areas to pay attention to and advice on pharmacotherapy. In case of questions, GPs could call a telephone line serviced by an endocrinologist during office hours.

**<H2>Control group**

For the usual care group, the programme comprised one annual comprehensive check-up, identical to the one received by the shared care group, plus three quarterly consultations with an endocrinologist. The quarterly consultations included control of BP, blood glucose, HbA\textsubscript{1c} and additional blood tests as needed.

**<H2>Study outcomes**

The primary outcome was the mean change in HbA\textsubscript{1c} between the groups from baseline to 12 months of follow-up. ‘Noninferiority’ for the shared care intervention was defined as a mean difference < 4.4 mmol/mol (0.4%) in HbA\textsubscript{1c} from baseline to 12 months of follow-up, in favour of usual care by comparing the shared care group with usual care group. The noninferiority margin was based on clinical judgement as well as the European Medicines Agency’s guidelines [19].

The secondary outcome was the proportion of participants fulfilling the total set of key quality indicators in the national Danish guidelines reflecting quality of care [20]. These contain a range of process measures covering seven parameters: HbA\textsubscript{1c}, BP, LDL-cholesterol, albumin excretion rate, fundoscopy, foot examination and smoking status (Table S2). We also evaluated the proportion of participants achieving treatment targets: HbA\textsubscript{1c} < 53 mmol/mol (7%), BP < 130/80 mmHg and LDL-cholesterol < 2.5mmol/l, plus achievement of all three targets combined.
Tertiary outcomes encompassed changes in BP, weight, waist-to-hip ratio, total cholesterol, triglycerides, HDL-cholesterol, LDL-cholesterol, albumin-to-creatinine excretion rate, as well as the perceived burden of diabetes related symptoms measured on Diabetes Symptom Checklist-Revised [21], and self-rated physical and mental health, measured by the Short-Form 36 (SF-36) questionnaire – Physical and Mental Component Score [22].

**Statistical analysis**

Power calculation was performed within the framework of noninferiority criteria based on the primary outcome HbA\(_1c\). With a noninferiority margin of 4.4 mmol/mol (0.4%) [16], a standard deviation of 10 mmol/mol (0.9%) [23], an alpha of 0.05 and a power of 0.8, as well as an estimated 10% discontinuity rate, the sample size was estimated to 140 participants.

The primary outcome was analysed for the per protocol (PP) population and rerun, for sensitivity reasons, for the intention to treat (ITT) population. The 90% confidence interval (CI) of the mean change in HbA\(_1c\) between the groups was analysed by conducting an unpaired \(t\)-test. For the primary outcome, noninferiority of shared care to usual care was claimed if the upper bound of the 90% CI was under the pre-specified noninferiority margin of 4.4 mmol/mol (0.4%). Then the \(P\)-value for noninferiority would be < 0.05, and noninferiority can be confirmed. In cases of missing responses due to withdrawal, we used the principle of last observed response carried forward.
To test the robustness of the data of the study completers, we conducted a tipping point analysis on the primary outcome. Participants who had dropped out were ascribed the mean 12 months’ follow-up HbA1c measurement for their treatment arm plus a stepwise penalty. At each step, we added an additional 1–2 mmol/mol (0.1–0.2%) and conducted the noninferiority tests as described previously. The tipping point was defined by the smallest penalty resulting in a $P$-value $\geq 0.05$.

The secondary and tertiary outcomes were evaluated in superiority analysis. Regarding the secondary outcome, possible differences between the two groups were tested in chi-square tests. The tertiary outcomes on continuous scales were tested by conducting analysis of covariance (ANCOVA), and outcomes on categorical scales were analysed by chi-square tests.

Data were analysed using SAS Enterprise Guide 7.1.

**Results**

Between August 2015 and December 2016, 146 participants were screened for an initial baseline visit at the outpatient clinic (Fig. 1). Six participants were excluded; thus 140 participants were randomized. They were distributed equally to the intervention and control group regardless of their pre-study treatment location ($P = 0.49$); in the intervention group, 49% were recruited from general practice and 51% from the outpatient clinic; in the usual care group, the distribution rate was 55% from general practice and 45% from the outpatient clinic. In total, 133 (95%) participants completed the 12 months’ follow-up. The median
number of consultations between baseline and the annual comprehensive check-up was three for both the shared care (range zero to three consultations) and the usual care group (range two to three consultations) \((P = 0.13)\).

**Baseline characteristics**

The shared care group and the control group were well matched at baseline in demographics and clinical characteristics as well as diabetes complications and treatment profiles (Table 1). Most of the participants were men (73.6%), with an average age of 65.0 years (95% CI 63.2–66.7) and a mean diabetes duration of 9.1 years (95% CI 8.0–10.2). Mean HbA1c was 52 mmol/mol (95% CI 50–53) (6.9%, 95% CI 6.8–7.1). In total, 95 (68%) participants had peripheral neuropathy, 26 (19%) had microalbuminuria and 21 (15%) had a previous major cardiovascular event.

**Primary outcome**

For study completers, the mean HbA1c change from baseline to 12 months’ follow-up was 2.3 mmol/mol (0.2%) in the shared care group and 1.0 mmol/mol (0.1%) in the usual care group. The between-group difference was 1.3 mmol/mol (90% CI –1.3, 3.9) (0.1%, 90% CI –0.1, 0.4). For the ITT population, the mean change from baseline was: 2.0 mmol/mol (0.2%) in the intervention group and 0.9 mmol/mol (0.1%) in the control group with a between-group difference of 1.1 mmol/mol (90% CI –1.5, 3.6) (0.1%, 90% CI –0.1, 0.3). Noninferiority was confirmed in both the PP \((n = 133)\) and ITT populations \((n = 140)\), as the upper limits of the 90% CI in the two analyses were below the predefined noninferiority margin of 4.4 mmol/mol (0.4%) (Fig. 2).
<H2>Secondary outcome</H2>

A total of 123 participants (92.5%) fulfilled all the key quality indicators of the Danish diabetes criteria of treatment quality: 62 of 66 participants (93.9%) in the shared care group and 61 of 67 participants (91.0%) in the usual care group ($P = 0.53$). Ten participants lacked one criterion each. Six participants had a LDL-cholesterol $>$ 2.5 mmol/l and did not receive lipid-lowering pharmacotherapy. Four participants had microalbuminuria and did not receive angiotensin-converting enzyme inhibitors or angiotensin receptor blockers. Figure 3 shows that compared with the shared care group, more participants in the usual care group achieved the blood pressure target after 12 months of follow-up; 17% and 37% respectively ($P < 0.01$). There were no significant differences between the groups with respect to achieving the targets for HbA$_1c$, LDL cholesterol or the three targets combined.

<H2>Tertiary outcomes</H2>

Table 2 shows that for the continuous variables, the only significant difference between the groups was the diastolic BP with a lower mean in the usual care group ($P = 0.04$). Additionally, there were no significant differences in the number of new cases of microalbuminuria; one in each group ($P = 0.94$). At 12 months’ follow-up, three participants in each group no longer had microalbuminuria. Additional tertiary outcomes are shown in Table S3.
<H1>Discussion</H1>

This study confirmed our hypothesis that shared care, consisting of one comprehensive check-up in an outpatient clinic plus three quarterly consultations in primary care practice per year, is noninferior to usual care in the outpatient clinic in the management of glycaemic control in people with Type 2 diabetes. This finding is in line with previous randomized shared care trials, where the effect of the intervention on mean HbA₁c was modest or absent [6,8,24–28]. However, it is difficult to compare the effect of our model with other shared care models as the interventions are multifaceted containing a variety of elements and with structures according to national and local healthcare systems. In this study, the mean baseline HbA₁c level was 52 mmol/mol in both groups. However, a previous shared care study did identify a greater reduction in HbA₁c among participants with hyperglycaemia compared with those with normoglycaemia [4]. In our study, participants with a baseline HbA₁c ≤ 53 mmol/mol (≤ 7%) (n = 82) increased the mean HbA₁c by an average of 5 mmol/mol (0.5%), whereas participants with a HbA₁c > 53 mmol/mol (> 7%) (n = 51) decreased the mean HbA₁c by 4 mmol/mol (0.4%) (P < 0.0001).

We found no significant differences between the groups either in number of participants fulfilling the Danish diabetes criteria of treatment quality or in the clinical or health-related quality-of-life outcomes. However, compared with the shared care group, the usual care group had a significant reduction in diastolic BP plus a greater proportion of participants achieving the BP target over time. BP measured in an outpatient clinic can be associated with a degree of imprecision. Yet, the differences in BP outcomes between the groups in this study might be due to therapeutic inertia among GPs. Previous studies have identified GPs as more reluctant to intensify treatment for people with Type 2 diabetes compared with specialists [26,27].

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To our knowledge, these results are the first from a randomized, noninferiority trial testing a shared care model for a Type 2 diabetes population. Most randomized shared care studies have been designed as superiority studies with usual care in primary care practice acting as control group [6,8,24,29,30] and rarely as noninferiority studies with usual care in the outpatient clinic as control group [28]. The latter is a randomized, noninferiority trial aiming to compare a community-based scheme run by GPs with special interest in Type 2 diabetes supported by an onsite endocrinologist [28]. The results of this study remain to be published.

In this study, both treatment arms provided satisfactory quality of care for the participants according to the Danish guidelines reflecting quality of care [20]. A total of 10 participants did not fulfil the outcomes regarding treatment for either dyslipidaemia or microalbuminuria. However, the numbers were small. In our shared care model, the vast majority of the criteria are part of the standard management programme for the annual comprehensive check-up, so the high fulfilment rates were expected. This is in line with other shared care studies, in which greater improvements in process measures were identified in groups receiving an annual review in an outpatient clinic compared with groups receiving usual care in primary care practice [8,31]. Process measures might be an integrated element or a point of attention in specialist care compared with care trajectories in primary care. According to a recent Norwegian study covering quality of care in primary care practice in 2005 and 2014, there were improvements in the number of people having their BP and cholesterol measured, but a decline in the proportion of both HbA1c measurements plus eye and albuminuria screenings [32].
One of the strengths of this study is the randomized controlled design. As described previously, many shared care studies are lacking randomization. Trials including randomization often use cluster randomization of the participating primary care practices [6,8,24,30]. First, to our knowledge, only a few previous studies testing a shared care model have randomized the participants [25,29]. Second, the 95% completion rate of study participants in our study is very high compared with other shared care studies on people with Type 2 diabetes [9,24,29,30]. Third, in the analysis of robustness of data, the tipping point was identified when adding a penalty of 20 mmol/mol to the primary outcome of the non-completers. Thus, the analyses of the secondary and tertiary outcomes, conducted on the data of the study completers, are appraised as robust. Finally, the patient population included was well-defined.

Some limitations need to be considered. Because we collaborated with only 29 of the 150 GPs in the hospital’s service area, the participating GPs might not be representative. If they hold a special interest in diabetes care, it could potentially bias the study and underestimate the 12 months’ follow-up results of the shared care group. The study is lacking patient-reported outcomes regarding satisfaction with the model of care. This will be investigated during the 24 months’ follow-up by use of questionnaires and interviews. Another limitation is the limited length of the follow-up period, as it can be difficult to discern clinically significant differences after 12 months of follow-up. A 3-year follow-up of the study is planned and will enlighten the sustainability of the study over time [16].
The findings of this study are most likely generalizable to the Danish healthcare system and probably also to other countries with similar healthcare systems. Even though many countries differ from the Danish tax-financed free-accessible healthcare services, the design of our study may still be of inspiration for other researchers.

Based on our study results, after 12 months of follow-up, the shared care programme is noninferior to an established programme in a specialized outpatient clinic in maintenance of glycaemic control of people with Type 2 diabetes and incipient complications. The study supports that shared care models could be part of future Type 2 diabetes management, as more people will benefit from the specialized diabetes team while keeping close contact with the general practitioner.

**Clinical implications**

Provided that the results are sustainable over time, the model can be implemented on a larger scale and allow more people to benefit from the specialized knowledge of the diabetes team. This could lead to more rational use of healthcare resources, and support the trend of chronic care shifting from the secondary to the primary care health sector [2].

**Funding sources**

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Competing interests

None declared.

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Author contributions

LM planned of the study, applied for funding, organized the recruitment of general practitioners, organized the recruitment of participants and the data collection, conducted the analyses and drafted the first manuscript. BBB organized the recruitment of participants and the data collection. DO planned the study, applied for funding and contributed to the interpretation of the results. HK planned the study and applied for funding. HM planned the study. NK planned the study. FKK planned the study. TV planned the study, applied for funding and contributed to the interpretation of the results. MER planned the study, applied for funding, organized the recruitment of primary care physicians and contributed to the interpretation of the results. All authors critically reviewed the drafts and read and approved the final version of the manuscript. LM and MER are the guarantors of this work and, as such, had full access to all the data.
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improving the quality of care for people with type 2 diabetes through a general practice

physician and endocrinologist coordination as the basis for diabetes care in clinical

Quality of care and outcomes in type 2 diabetic patients: a comparison between general

to inadequate glycemic control: do specialists differ from primary care physicians?
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FIGURE 2 Between-group differences in HbA1c from baseline to 12 months of follow-up. CI, confidence interval.

FIGURE 3 Proportion of patients achieving treatment targets at baseline and after 12 months of follow-up. *Between-group differences at 12 months’ follow-up. †Integration of all three target levels.

Supporting Information
Additional Supporting Information may be found in the online version of this article.

Figure S1. The Danish Risk Stratification Model.

Table S1. Demographic and clinical characteristics regarding referral status.

Table S2. Quality of care criteria – Danish Adult Diabetes Registry.

Table S3. Changes in additional tertiary outcomes from baseline between the shared care and the usual care group.
Table 1. Demographics and clinical characteristics

<table>
<thead>
<tr>
<th></th>
<th>Shared care (n = 71)</th>
<th>Usual care (n = 69)</th>
<th>P-value§</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years, range)</td>
<td>63.5 (60.9–66.2)</td>
<td>66.4 (64.2–68.6)</td>
<td>0.10</td>
</tr>
<tr>
<td>Men n (%)</td>
<td>52 (73.2)</td>
<td>51 (73.9)</td>
<td>0.93</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>31.0 (29.9–32.2)</td>
<td>30.6 (29.2–32.1)</td>
<td>0.67</td>
</tr>
<tr>
<td>Current smoker n (%)</td>
<td>9 (12.7)</td>
<td>17 (25.0)</td>
<td>0.06</td>
</tr>
<tr>
<td>Diabetes duration (years)</td>
<td>8.7 (7.1-10.2)</td>
<td>9.6 (8.1-11.1)</td>
<td>0.37</td>
</tr>
<tr>
<td>Systolic BP (mmHg)</td>
<td>135.8 (133–138.7)</td>
<td>135.3 (132.1–138.6)</td>
<td>0.82</td>
</tr>
<tr>
<td>Diastolic BP (mmHg)</td>
<td>77.3 (75.3–79.3)</td>
<td>76.9 (75–78.9)</td>
<td>0.77</td>
</tr>
<tr>
<td>HbA₁c (mmol/mol)</td>
<td>52 (50–54)</td>
<td>52 (50–54)</td>
<td>0.94</td>
</tr>
<tr>
<td>HbA₁c (%)</td>
<td>6.9 (6.7–7.1)</td>
<td>6.9 (6.7–7.1)</td>
<td>0.94</td>
</tr>
<tr>
<td>Fasting plasma glucose (mmol/l)*</td>
<td>8.7 (8.1–9.3)</td>
<td>9.0 (8.4–9.5)</td>
<td>0.48</td>
</tr>
<tr>
<td>LDL-cholesterol (mmol/l)†</td>
<td>2.0 (1.8–2.1)</td>
<td>2.2 (1.9–2.4)</td>
<td>0.14</td>
</tr>
<tr>
<td>Non-proliferative diabetic retinopathy or maculopathy n (%)</td>
<td>8 (11.3)</td>
<td>6 (8.7)</td>
<td>0.61</td>
</tr>
<tr>
<td>Peripheral neuropathy n (%)</td>
<td>47 (68.1)</td>
<td>48 (70.6)</td>
<td>0.67</td>
</tr>
<tr>
<td>Microalbuminuria n (%)</td>
<td>14 (19.7)</td>
<td>12 (17.4)</td>
<td>0.72</td>
</tr>
<tr>
<td>Former major cardiovascular event n (%)</td>
<td>8 (11.3)</td>
<td>13 (18.8)</td>
<td>0.21</td>
</tr>
<tr>
<td>Ischemic heart disease n (%)‡</td>
<td>5 (7.0)</td>
<td>5 (7.2)</td>
<td>0.96</td>
</tr>
<tr>
<td>Anti-diabetic therapy n (%)</td>
<td>6 (8.5)</td>
<td>6 (8.7)</td>
<td>0.96</td>
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<tr>
<td>Non-pharmacological</td>
<td>64 (90.1)</td>
<td>62 (89.9)</td>
<td>0.96</td>
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<tr>
<td>Oral anti-diabetic drugs</td>
<td>12 (16.9)</td>
<td>17 (24.6)</td>
<td>0.26</td>
</tr>
<tr>
<td>Glucagon-like peptide-1 receptor agonists</td>
<td>7 (9.9)</td>
<td>12 (17.4)</td>
<td>0.21</td>
</tr>
</tbody>
</table>

Values are mean (95% CL for the mean) unless stated otherwise.

Missing data due to *non-fasting (n = 8), †high levels of triglycerides (n = 2) and failed analyses (n = 1).

‡Without former major cardiovascular event.

§Differences between the groups were analysed using Student’s t-test or Wilcoxon–Mann–Whitney test for continuous variables and Pearson’s chi-squared for categorical variables.

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**Table 2. Changes in tertiary outcomes from baseline between the shared care and the usual care group**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Shared care (n = 66)</th>
<th>Usual care (n = 67)</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Baseline</td>
<td>Month 12</td>
</tr>
<tr>
<td>Systolic BP (mmHg)</td>
<td>66</td>
<td>136.5</td>
<td>137.0</td>
</tr>
<tr>
<td>Diastolic BP (mmHg)</td>
<td>66</td>
<td>77.3</td>
<td>77.4</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>65</td>
<td>3.9</td>
<td>3.8</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>65</td>
<td>1.8</td>
<td>1.9</td>
</tr>
<tr>
<td>HDL-cholesterol (mmol/l)</td>
<td>65</td>
<td>1.2</td>
<td>1.2</td>
</tr>
<tr>
<td>LDL-cholesterol (mmol/l)</td>
<td>64</td>
<td>1.9</td>
<td>1.8</td>
</tr>
<tr>
<td>U-ACR</td>
<td>65</td>
<td>30.1</td>
<td>27.2</td>
</tr>
<tr>
<td>Body weight (kg)</td>
<td>66</td>
<td>94.0</td>
<td>93.4</td>
</tr>
<tr>
<td>Hip-to-waist ratio</td>
<td>66</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>PCS</td>
<td>56</td>
<td>48.4</td>
<td>48.3</td>
</tr>
<tr>
<td>MCS</td>
<td>57</td>
<td>55.2</td>
<td>54.4</td>
</tr>
<tr>
<td>DSC-R</td>
<td>62</td>
<td>0.9</td>
<td>1.0</td>
</tr>
</tbody>
</table>

Mean ± SEM. *Analyses of covariance (ANCOVA) used for testing differences between the groups.

DSC-R, Diabetes Symptom Checklist-Revised; MCS, Mental Component Scale; PCS, Physical Component Scale; U-ACR, urine albumin to creatinine ratio.