






## Original Research

# A pilot study of Pharmacist-Dietician Collaborative support and Advice (PDCA) for patients with type 2 diabetes in community pharmacy: A single-arm, pre-post study

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### Abstract

**Background:** In Japan, there is a pressing need to improve community health care to cope with the rapid aging of the population. In this context, there have been private-sector-led approaches to enhance community dietary support by employing dietitians in pharmacies. **Objectives:** To evaluate the effects of collaboration between dietitians and pharmacists working in pharmacies to support patients with type 2 diabetes. **Methods:** A single group pre- and post-comparative study was conducted on patients with type 2 diabetes mellitus. The intervention period was 6 months. During the intervention period, the dietitians provided dietary support to the patients after first providing them with medication guidance. The contents of these instructions were shared with the pharmacists. The contents of the instructions were recorded, and confirmed in monthly meetings with the principal investigator. The primary endpoint was the Hemoglobin A1c (HbA1c) level, and the secondary endpoints were high-density lipoprotein-cholesterol (HDL-c), low-density lipoprotein-cholesterol (LDL-c), Triglyceride (TG), degree of dietary self-management, degree of unbalanced diet and satisfaction with pharmacy services. **Results:** Eight patients completed the intervention period. The first patient's intervention started in March 2021, and all patients' interventions were completed by December 2021. The primary endpoint, the mean (SD) HbA1c, was 7.26 (0.96) at baseline and decreased to 6.63 (0.79) after 6 months ( $p=0.028$ ,  $r=0.72$ ). Also, the HDL-c increased from 55.00 (14.81) to 63.14 (10.11) ( $p=0.110$ ,  $r=0.51$ ) and the Diabetes Mellitus Dietary Self Efficacy Scale score increased from 51.67 (8.31) to 60.17 (8.45) ( $p=0.025$ ,  $r=0.79$ ) and the patient satisfaction score increased 24.0 (4.0) to 26.1 (3.3) ( $p=0.161$ ,  $r=0.51$ ). Moderate decreases were also observed in LDL-c ( $p=0.235$ ,  $r=0.47$ ) and TG ( $p=0.368$ ,  $r=0.37$ ). **Conclusions:** Collaboration between dietitians and pharmacists working in pharmacies may improve the dietary habits and glycemic control of patients with type 2 diabetes. To verify this hypothesis more reliably, randomized controlled trials need to be conducted.

**Keywords:** Community pharmacy; Dietitians; Collaboration; Type 2 diabetes

## INTRODUCTION

Diabetes mellitus causes various complications, such as retinopathy, neuropathy, and nephropathy and treatment, including lifestyle modification, is required from an early stage.<sup>1,2</sup> In Japan, medical costs related to the treatment of diabetes exceed 1.2 trillion yen per year,<sup>3</sup> and the Ministry of Health, Labour and Welfare (MHLW) has designated diabetes as one of the most critical diseases to monitor. In order to improve the lives of patients, it is necessary to have a good knowledge of their background and lifestyle and for this reason, the role of community medicine is significant. The role of pharmacies in providing health support to the community has also been

actively discussed, as shown by The Asheville Project<sup>4,5</sup> and the published results from various randomized control trials RCTs.<sup>6,7</sup> In Japan, there have been efforts to implement a Japanese version of the Asheville Project<sup>8</sup> and RCTs<sup>9,10</sup> showing the effectiveness of lifestyle modification support by pharmacy pharmacists for diabetic patients have been conducted.

Yaghoubi M et al. conducted a meta-analysis of these studies and showed that the interventions of pharmacy pharmacists can be expected to lower blood glucose levels in patients with type 2 diabetes.<sup>11</sup> However, despite the popularity of these studies, pharmacists lack confidence in their ability to provide lifestyle support to patients.<sup>11,12</sup> Against this background, the private sector in Japan has begun to take the initiative in placing dietitians in pharmacies.<sup>13</sup> In these pharmacies, dietitians are employed concurrently as dispensing clerks, and are expected to provide dietary support to patients in between their work as dispensing clerks.<sup>14</sup> This approach has clinically rich potential, as it can simplify access to dietary therapy for patients and can have a positive impact on avoiding hypoglycemia. However, it has been pointed out that pharmacies often lack the infrastructure to educate dietitians and that dietitians feel that they are not able to use their expertise due to their already busy workload as dispensing clerks.<sup>15</sup> We conducted an interventional study to examine the effects of continuous patient support by dietitians working in such pharmacies. We hereby report the results of this pilot study.

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## OBJECTIVE

The aim of this study was to examine the effects of dietary support for patients with type 2 diabetes through collaboration between dietitians and pharmacists working in pharmacies.

## METHODS

### Study design

This study was a single-arm, pre-post comparative study. The intervention period was 6 months. During the intervention period, dietary counseling was provided to patients by a dietitian working at a pharmacy and medication guidance was then provided by a pharmacist.

### Inclusion and exclusion criteria of the study

The patients enrolled in this study were type 2 diabetic patients on medication, aged 20-80 years. The exclusion criteria were as follows: serious complications (retina, gangrene of lower limbs, dialysis), abnormalities in chewing and swallowing functions, receipt of other private dietary support services, a history of psychiatric or neurological disorders and a history of malignancy.

### Training

Prior to the intervention period, a three-hour online study explanation and training session was provided to the dietitians involved in the intervention. The training was conducted under the supervision of a diabetologist and included role-playing on how to listen to dietary habits and provide dietary support to diabetic patients. In addition, video materials were posted on YouTube (limited access) so that they could be viewed as needed. In addition, four types of booklets were prepared and the dietitians were told to distribute them as needed. During the intervention period, an online meeting was held once a month for about 30 minutes between the primary investigator (PI) and the dietitian at each store. When necessary, the PI referred the participants to the co-investigator, a diabetologist.

### Outcomes

The primary outcome was the change in Hemoglobin A1c (HbA1c). The secondary outcomes were low-density lipoprotein-cholesterol (LDL-c), Triglyceride (TG), high-density lipoprotein-cholesterol (HDL-c), degree of unbalanced diet, degree of dietary self-management and satisfaction with pharmacy services. Blood test data were obtained by asking the patients to bring the results received during their clinic visits to the pharmacy. The degree of unbalanced diet, degree of dietary self-management and satisfaction with pharmacy services were obtained by distributing the questionnaires to the patients at the pharmacy and having them fill them out on the spot. In order to reduce the potential for bias caused by patients hesitating to answer the questionnaires, the completed questionnaires were submitted in envelopes that were not accessible to the pharmacy staff. To assess the degree of unbalanced diet, we used a Henshoku scale developed by Imada et al.<sup>16</sup> The Henshoku scale consists of 15 questions to be answered using a 4-point scale. The highest score is 60 and

the lowest score is 15. Lower scores indicate more balanced diets. To assess the degree of dietary self-management, we used the Diabetes Mellitus Dietary Self Efficacy Scale (DMDSES)<sup>17</sup> developed by Yasukata et al. The DMDSES is a 15-item questionnaire with a six-point scale. A higher score indicates higher self-efficacy for dietary therapy for diabetes. For the satisfaction with pharmacy services questionnaire, a 10-item questionnaire developed by Armand et al. was used. This questionnaire uses a 5-point scale, with higher scores indicating greater satisfaction with pharmacy services.<sup>18</sup>

### Statistical analysis

Comparison of each outcome at the beginning and end of the intervention was made by paired t test and the effect size ( $r$ )<sup>19</sup> was determined. The criteria for determining the size of the effect were as follows: >0.5: large, 0.5-0.3: moderate, 0.1-0.3: small.

The risk rate of the paired t test was set at 5%. All analyses were performed using IBM SPSS Statistics 27 (IBM Japan, Tokyo).

## RESULTS

Nine patients were recruited for the study at three pharmacies. One person dropped out during the intervention period. An analysis was conducted on the 8 patients who completed the intervention period. The information of the patients included in the analysis is shown in Table 1. The mean age was 70.1 years and 62.5% of the patients were male. Half of the patients had complications of hypertension or dyslipidemia. The physical activity level was 1 in 75.0% and 3 in 25.0%. None of the patients smoked and 37.5% drank alcohol.

The changes in the primary and secondary endpoints from baseline to 6 months are shown in Table 2. The mean (SD) of HbA1c, the primary endpoint, was 7.3 (1.0) at baseline and

| Patients attributes         |                  |            |
|-----------------------------|------------------|------------|
| Age Mean (SD)               |                  | 70.1 (7.0) |
| Sex (male (%))              |                  | 62.5       |
| Complications (%)*          | HT               | 50.0       |
|                             | DL               | 50.0       |
|                             | HU               | 12.5       |
|                             | Others           | 25.0       |
|                             | No complications | 25.0       |
| Physical activity level (%) | 1                | 75.0       |
|                             | 3                | 25.0       |
| Family composition (%)      | Single           | 25.0       |
|                             | With spouse      | 75.0       |
| Smoking habits (%)          |                  | 0.0        |
| Alcohol habits (%)          |                  | 37.5       |

SD: standard deviation

\*HT: hypertension, DL: dyslipidemia, HU: hyperuricemia

Others: duodenum ulcer (n=1), Osteoporosis (n=1)



decreased to 6.6 (0.8) after 6 months ( $p=0.028$ ,  $r=0.72$ ). Also, the HDL-c increased from 55.0 (14.8) to 63.1 (10.1) ( $p=0.110$ ,  $r=0.51$ ), and the DMDSES score increased from 51.7 (8.3) to 60.2 (8.4) ( $p=0.025$ ,  $r=0.79$ ), the satisfaction score increased from 24.0 (4.0) to 26.1 (3.3) ( $p=0.161$ ,  $r=0.51$ ). Moderate decreases were also observed in LDL-c ( $p=0.235$ ,  $r=0.47$ ) and TG ( $p=0.368$ ,  $r=0.37$ ).

## DISCUSSION

In this study, we conducted a single-arm, pre-post study to examine the effects of collaboration between dietitians and

|                | Baseline Mean (SD) | After 6 months Mean (SD) | P value | Effect size (r) |
|----------------|--------------------|--------------------------|---------|-----------------|
| HbA1c (%)      | 7.3 (1.0)          | 6.6 (0.8)                | 0.028   | 0.72            |
| LDL-c          | 98.0 (28.6)        | 89.0 (17.0)              | 0.235   | 0.47            |
| TG             | 144.0 (30.4)       | 125.4 (33.0)             | 0.368   | 0.37            |
| HDL-c          | 55.0 (14.8)        | 63.1 (10.1)              | 0.110   | 0.51            |
| Henshoku-scale | 21.1 (5.6)         | 23.1 (4.6)               | 0.074   | 0.66            |
| DMDSES         | 51.7 (8.3)         | 60.2 (8.4)               | 0.025   | 0.79            |
| Satisfaction   | 24.0 (4.0)         | 26.1 (3.3)               | 0.161   | 0.51            |

HbA1c: Hemoglobin A1c level, LDL-c: low-density lipoprotein-cholesterol, TG: Triglyceride, HDL-c: high-density lipoprotein-cholesterol, DMDSES: The Diabetes Mellitus Dietary Self Efficacy Scale

pharmacists working in pharmacies in Japan on supporting patients with type 2 diabetes. A 6-month intervention resulted in a significant decrease in HbA1c, a significant increase in HDL-c, and an increase in the degree of dietary self-management and satisfaction score. Many studies have shown that collaborative interventions can improve glycemic control,<sup>20-22</sup> but as far as the authors know, there have been no previous studies investigating the effects of collaboration between dietitians and pharmacists working in pharmacies. Many previous studies have shown that interventions aimed at improving lifestyle habits can be expected to reduce HbA1c by about 0.6<sup>11</sup> and this pilot study yielded results exactly in line with those previously reported. In addition, the HDL-c increased by nearly 15% in this study. An increase in HDL-c is a useful factor to indicate improvement in lifestyle: it has been reported that physical activity, smoking cessation, weight loss, alcohol consumption, Mediterranean diet, etc. can result in an increase in HDL-c.<sup>23</sup> In this study, as well, changes in patients' lifestyles can be inferred from these results. Although the changes in the LDL-c and TG values were not statistically significant, we believe that more definite effects can be expected to appear with continued intervention. The improvement in the degree of dietary self-management assessed by the DMDSES had the largest effect size of all the outcomes. This may be due to the fact that the dietitian provided continuous dietary advice over a period of 6 months, which encouraged the patients to develop healthy eating

habits and helped them follow the dietary regimen. On the other hand, the score of the Henshoku scale tended to worsen over the intervention period, although this was not statistically significant. We believe that one of the reasons for this may be that the patients at the beginning of the intervention were not able to correctly evaluate the degree of their own unbalanced diet and became able to evaluate it correctly as a result of the continuous dietary support from the dietitian.

There was only one dropout in this study, which suggests that the design of the study was not overwhelming for any of the dietitians, pharmacists, or patients. We also believe that the monthly follow-up by the principal investigator was one of the factors that reduced the number of dropouts. Furthermore, we believe that this follow-up contributed to maintaining the motivation of the interventionists and the quality of the interventions.

The limitations of this study are as follows. First, this was a pilot study with a small number of subjects. Second, it was a single-group study, so we cannot be sure of causality. Thirdly, it was not possible to objectively assess the changes in the patients' eating habits. Although the brief-type self-administered diet history questionnaire (BDHQ) is a standard questionnaire for dietary habits, it has 80 questions and requires a lot of time to answer, so we decided that it was not suitable for answering in a pharmacy waiting room. Furthermore, even this questionnaire cannot be said to be objective, as it is left to the subjectivity of the respondents.

Despite the above limitations, we believe that this study is significant as it proposes a new and effective form of diabetes care in community medicine.

## CONCLUSION

Dietary collaborative support by pharmacy dietitians and pharmacists may improve the dietary habits of patients with type 2 diabetes and improve their glycemic control status.

## DECLARATIONS

### Author's contributions

MS designed and conducted the study, analyzed the data, and wrote the manuscript. NS provided general research advising. NI and KS assisted in conducting the study. MO provided general research advising. All authors read and approved the final manuscript.

### Funding

This study was supported by the Policy-Based Medical Services Foundation.

### Availability of data and materials

Supporting data for the findings of this study are available from the corresponding author on request. The data are not publicly available for privacy and ethical reasons.



### Ethics approval and consent to participate

This study was conducted in compliance with the ethical guidelines for “Medical Research Involving Human Subjects.” This study was conducted with the approval of the Research Ethics Review Committee of the Osaka University of Pharmaceutical sciences (currently Osaka Medical and Pharmaceutical University) (Approval No: 0072). Informed consent was obtained from all study participants prior to their participation. This study is registered with University Hospital

Medical Information Network (UMIN000040102).

### Conflicts of interest

There are no conflicts of interest to declare.

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