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# Evaluation of clinical efficacy of continuous care with improved insulin injection techniques on patients with diabetes mellitus: a randomized controlled trial

**Fang-Ying Zhang*, Mengyuan Shen* and Li-Qin Sun**

**Abstract**

**Objective:** To investigate the clinical effect of continuous care with improved insulin injection techniques on patients with diabetes mellitus.

**Methods:** This randomized controlled trial enrolled patients with diabetes mellitus. They were randomly assigned to a control or observation group. Patients in the control group received conventional continuous nursing. Patients in the observation group were given optimized insulin injection education and continuous nursing on the same basis as the conventional nursing used in the control group. Blood glucose-related outcomes, knowledge of insulin injections and adverse events were recorded.

**Results:** A total of 96 patients with diabetes mellitus were enrolled in the study ($n = 48$ per group). There were no significant differences between the two groups in terms of sex, age and glycosylated haemoglobin ($HbA_{1c}$). Compared with the control group, continuous care combined with optimized insulin injection techniques significantly reduced blood glucose target time, fasting blood glucose, 2-h postprandial blood glucose and $HbA_{1c}$. The proportions of patients reporting a subcutaneous mass, insulin leakage and hypoglycaemic events were significantly lower in the observation group; and pain scores were significantly reduced compared with the control group.

**Conclusions:** Continuous care and optimization of insulin injection techniques can help patients achieve better diabetes-related outcomes.

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*These authors contributed equally to this work.

**Corresponding author:**
Fang-Ying Zhang, Department of Endocrinology, The First People's Hospital, 429 Beihuan Road, Fuchun Street, Fuyang District, Zhejiang Hangzhou 310000, China.
Email: zhanfy120@163.com

Department of Endocrinology, The First People's Hospital of Fuyang District, Hangzhou, Zhejiang Province, China

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Continuity care, insulin injection techniques, diabetes, clinical efficacy

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## Introduction

Diabetes mellitus is a chronic disease that is characterized by persistently high blood glucose levels and it is the sixth leading cause of death in the world.[1] According to statistics, the mortality associated with type 2 diabetes mellitus and its related complications accounts for 8.4% of the worldwide mortality.[2] Chronic hyperglycaemia induces the apoptosis of islet beta cells, islet endothelial cells and endothelial cells through an intrinsic apoptotic pathway, leading to an increased risk of atherosclerotic vascular disease and diabetes-related acute thrombotic events.[3] Many studies have shown that insulin injections are currently the most effective treatment for diabetes mellitus.[4] However, there are still many problems with insulin injections. Insulin injections are mainly carried out at home, but traditional nursing cannot carry out comprehensive long-term monitoring of patients and diabetes control is a long-term process, so these factors can lead to a significant increase in the complications associated with insulin injections.[5] Therefore, patients with diabetes mellitus are in urgent need of comprehensive professional nursing methods and technical guidance for administering their own insulin injections.[6]

Modern medicine focuses not only on the treatment of chronic diseases, but also on the quality of care that patients might receive during the course of their treatment.[7] In recent years, due to the rapid development in the field of nursing research at home and abroad, continuous nursing has gradually attracted attention. Continuous care refers to the form of open and extended nursing services provided by telephone, e-mail, WeChat, home care and other information tools. Its main purpose is to provide ongoing and effective healthcare, health promotion and guidance services to discharged patients.[8] The aim of continuous nursing is to influence patients through more comprehensive care, to correct bad behaviour patterns and to promote early recovery.[9] Since diabetes mellitus is a relatively common chronic disease in clinical practice and its treatment is also a long-term process, the role of nursing in the treatment of diabetes mellitus is worth exploring.[10,11]

Recent research has revealed that non-standard insulin injection is common throughout the world.[12] Many patients with diabetes mellitus cannot control their blood glucose levels to bring them close to normal levels even with insulin treatment.[13] Insulin injection technology is one of the key factors causing hypoglycaemic events.[14] A recent study found that high-quality nursing can effectively improve the blood glucose level and psychological state of patients with gestational diabetes mellitus; and improve the treatment efficiency.[15] It can be seen that nursing mode and insulin injection technology play an important role in the treatment of patients with diabetes mellitus. Therefore, this study was conducted to examine the clinical effect of improved insulin injection techniques in the treatment of diabetes mellitus under the guidance of continuous nursing.

## Patients and methods

### Study design and population

This randomized controlled trial enrolled patients with diabetes mellitus that were admitted to the Department of Endocrinology, The First People's Hospital of Fuyang District, Hangzhou, Zhejiang Province, China between August 2019 and August 2021. The inclusion criteria were as follows: (i) patients that met the World Health Organization diagnostic criteria for diabetes mellitus; (ii) insulin injection was required for the first time; (iii) patients that volunteered to participate in the study; (iv) patients that were able to communicate without language barriers and they had the normal ability to understand and accept instructions. The exclusion criteria were as follows: (i) patients with severe malignant tumours; (ii) patients with infectious diseases; (iii) patients with acute myocardial infarction; (iv) patients with liver and kidney dysfunction; (v) patients with cerebrovascular diseases and other complications; (vi) patients with cognitive impairment; (vii) an insulin pump had been used; (viii) patients with unable to cooperate to complete the investigation.

This study was approved by the Ethics Committee of The First People's Hospital of Fuyang District, Hangzhou, Zhejiang Province, China on 20 October 2021 (no: 2021-100). Written informed consent was obtained from all participants enrolled in the study. The reporting of this study conforms to the Consolidated Standards of Reporting Trials (CONSORT) statements.[16] All procedures that involved human participants were undertaken in accordance with the ethical standards of the Institutional and National Research Committee, with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. In error, this trial was not registered prospectively, but it was registered retrospectively at the Chinese Clinical Trial Registry (registration no. ChiCTR2200057166).

### Randomization and interventions

The study participants were randomly allocated to each group using a computer-generated randomization schedule. Patients in the control group received a conventional continuous nursing intervention. Patients in the observation group were given optimized insulin injection education and continuous nursing on the basis of the conventional nursing intervention used in the control group.

For the optimized insulin injection education, the specialist nurses used routine nursing methods to guide patients to learn insulin injection techniques. This included an initial oral description, distribution of an education manual and then the correct injection method was physically demonstrated. The continuous care nurses instructed patients to learn the technique of insulin injection and completed the continuous care within 6 months after patients left the hospital. The specific nursing guidance was as follows: (i) psychological guidance: when the patient was admitted to hospital, the psychological state of the patient was evaluated first. Nurses then encouraged the enthusiasm of the patients so that they would better cooperate with the treatment. At the same time, different psychological guidance was designed for different patients. For patients with long-term chronic conditions, the influence of mental factors on the disease was explained to them, they were encouraged to maintain a good mood and those with liver disease were advised to abstain from anger. A patient communication group was established to encourage patients to communicate with each other, relieve psychological pressure and to guide patients in a healthier direction; (ii) dietary guidance: diet plays an

important role in the treatment of many diseases. Dietary education, according to the doctor's instructions, was provided to patients and their families so that they fully understood the role of diet on disease control. Taking the diabetic diet as an example, in general, patients with diabetes mellitus should consume a diet composed of 45% fat, 22% protein and 33% carbohydrate. Patients with diabetes should eat as close to the standard diet as possible, while nurses provided personalized guidance programmes based on the patient's condition, eating habits and ability to pay. The patient's family recorded the patient's daily dietary intake so that the nurses could provide more accurate guidance on the patient's diet; (iii) discharge nursing guidance: during the hospital stay, the continuity care team helped patients to learn about insulin injection techniques, the steps involved in the installation and use of insulin pens, injection site selection and rotation, injection time and other precautions, personalized injection time and dose. Information was provided in a small book distributed to patients, regular weekly education of patients after discharge, regular follow-up of patients and contact with the patient's family to regularly record and monitor the patient's injection situation, fill out the insulin injection technical questionnaire and collect timely feedback. In addition, according to the patient's condition, especially elderly patients, they were informed in detail of the matters that needed attention after discharge, medication guidance, and the time and place of follow-up by telephone, mail and other means. When the patient was discharged from the hospital, their satisfaction with their medical services during their hospital stay was determined by a questionnaire and their opinions and suggestions were carefully listened to. In addition, the nurses aimed to understand the patient's family and community environment; and to provide appropriate advice on the selection of assistive devices and the use of community resources after discharge, so as to develop rehabilitation plans.

### *Knowledge of insulin injection*

A questionnaire about insulin injection knowledge was designed. The questionnaire included questions that assessed their knowledge of the preparation before injection, goal of insulin injections and actual target, medicine, injection technology operation, knowledge of injection site rotation, common complications and insulin injection-related problems. There were 20 single-choice questions in the questionnaire, with a correct answer of 5 points and no score for wrong answers. The maximum total number of points was 100 and the patient was given 20 min to complete the questionnaire. The higher the score, the better the knowledge of insulin injections. Diabetes-related training was initiated at the beginning of the study and continued within 6 months of discharge. The questionnaire was administered at 6 months after hospital discharge.

### *Hypoglycaemic effects*

Fasting blood glucose (FBG) and 2-h postprandial blood glucose (2-h PBG) were measured on the first day of the study and every 3 days thereafter until the end of follow-up at 6 months after discharge. Glycosylated haemoglobin ($HbA_{1c}$) was measured on the first day of the study and every 3 months thereafter until the end of the 6-month follow-up after discharge. Blood glucose levels were measured using a RIGHTEST$^{TM}$ GM300 glucose meter (Bionime [Shanghai], Shanghai, China). Venous blood samples were obtained from all participants after an 8-h fast and at 2 h after their breakfast. A sterile test tube containing 2 g/l sodium fluoride was used to

collect the whole venous blood samples. A RIGHTEST$^{TM}$ GM300 glucose meter (Bionime [Shanghai]) was used to measure the FBG and 2-h PBG concentrations. All samples used for the determination of $HbA_{1c}$ were anticoagulated with 1.8 mg/ml ethylenediaminetetraacetic acid and analysed using an automatic analyser (D-10$^{TM}$ Hemoglobin detection system; Bio-Rad, Hercules, CA, USA).

### *Injection site adverse reactions*

During hospitalization, the nurses guided the patients to observe and record the skin conditions of the injection area, including subcutaneous mass, insulin leakage and hypoglycaemic events within 6 months. Insulin leakage was assessed by using dry cotton swabs to cover the skin at the injection site immediately after insulin injection and several cotton swabs to absorb fluid. The designated nurses evaluated the adverse reactions of the injection site by multiple methods such as appointments to return to the hospital for follow-up visits, home visits, telephone follow-ups or other ways after discharge. Pain was evaluated using a visual analogue scale, with a total score of 10 points (>4 points for pain; ≤4 points for no pain).

### *Statistical analyses*

All statistical analyses were performed using IBM SPSS Statistics for Windows, Version 23.0 (IBM Corp., Armonk, NY, USA). Normally distributed continuous data are presented as mean ± SD and compared using Student's *t*-test. Categorical data are presented as *n* of patients (%) and compared using $\chi^2$-test. A $P < 0.05$ was considered statistically significant.

## Results

This randomized controlled trial enrolled 96 patients with diabetes mellitus (Figure 1). Of these, 14 had type 1 diabetes mellitus and 82 had type 2 diabetes mellitus. They were randomly divided equally into the observation and control groups ($n = 48$ per group). The clinical characteristics of the two groups are presented in Table 1. In the control group, there were 25 females and 23 males with a mean ± SD age of 55.92 ± 11.98 years (range, 30–75 years) and a mean ± SD $HbA_{1c}$ of 6.37 ± 1.14%. In the observation group, there were 26 females and 22 males with a mean ± SD age of 52.63 ± 11.82 years (range, 27–73 years) and a mean ± SD $HbA_{1c}$ of 6.27 ± 0.96%. There were no significant differences between the two groups in terms of sex, age and $HbA_{1c}$.

After providing different nursing and diabetes mellitus-related training to the two study groups, the results showed that compared with the control group, the knowledge of insulin injections in the observation group was significantly better (Table 2). Specifically, the differences were significant between the two groups for 15 of the 20 questions ($P < 0.05$ for all comparisons).

Compared with the control group, blood glucose target time, FBG, 2-h PBG and $HbA_{1c}$ of the observation group were significantly lower at the end of the 6-month observation period ($P < 0.05$ for all comparisons) (Table 3).

Compared with the control group, the proportion of patients reporting a subcutaneous mass, insulin leakage and hypoglycaemic events during the 6-month observation period was significantly lower in the observation group ($P < 0.05$ for all comparisons) (Table 4). The pain scores were significantly reduced in the observation group compared with the control group during the 6-month observation period ($P = 0.001$).

## Discussion

Diabetes mellitus is a complex and constantly changing chronic disease.[17] A large

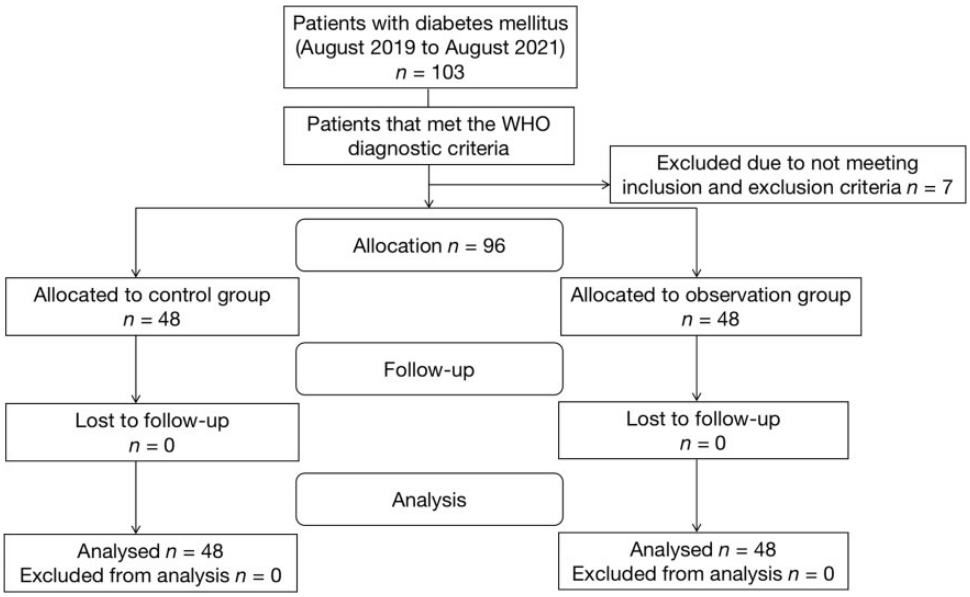


**Figure 1.** Flow chart showing progress through enrolment, randomization and analysis of patients with diabetes mellitus that were enrolled in a study to investigate the clinical effect of improved insulin injection techniques in the treatment of diabetes mellitus under the guidance of continuous nursing. WHO, World Health Organization.

**Table 1.** Demographic and clinical characteristics of patients with diabetes mellitus that were enrolled in a study to investigate the clinical effect of improved insulin injection techniques in the treatment of diabetes mellitus under the guidance of continuous nursing.

| Characteristic | Control group $n = 48$ | Observation group $n = 48$ |
|---|---|---|
| Age, years | $55.92 \pm 11.98$ | $52.63 \pm 11.82$ |
| Sex | | |
| Male | 23 | 22 |
| Female | 25 | 26 |
| $HbA_{1c}$, % | $6.37 \pm 1.14$ | $6.27 \pm 0.96$ |

Data presented as mean ± SD or *n* of patients.
No significant between-group differences ($P \geq 0.05$); continuous data were compared using Student's *t*-test and categorical data were compared using $\chi^2$-test.
$HbA_{1c}$, glycosylated haemoglobin.

number of studies have found that the prevalence of diabetes is increasing year by year, threatening the health and life of tens of thousands of people.[18–20] Good glycaemic control helps to reduce the risk of diabetes-related complications.[21]

In recent years, numerous studies have found that during hospitalization, most patients with diabetes mellitus are exposed to traditional nursing, including basic nursing such as the monitoring of basic vital signs at admission, daily blood glucose level measurements, diet management, morning and evening education.[22,23] Different from traditional nursing, continuous nursing can enable discharged patients to receive continuous healthcare during their recovery, thereby promoting patient recovery, reducing the need for rehospitalization due to deterioration of the condition and reducing the cost of health services.[24,25] The main components of continuous healthcare include scientific guidance about the daily diet of patients during hospitalization, the formulation of practical exercise plans for patients and efforts to

**Table 2.** The results of the analysis of the insulin injection knowledge at 6 months after discharge of patients with diabetes mellitus that were enrolled in a study to investigate the clinical effect of improved insulin injection techniques in the treatment of diabetes mellitus under the guidance of continuous nursing.

| Question number | Question | Number of correct answers | | Statistical analyses[a] |
|---|---|---|---|---|
| | | Control group $n = 48$ | Observation group $n = 48$ | |
| 1 | Know your target for $HbA_{1c}$ level | 10 | 40 | $P = 0.025$ |
| 2 | After insulin injection, the needle should stay in place for at least 10 seconds before pulling out | 20 | 41 | $P < 0.001$ |
| 3 | Unopened insulin should be refrigerated at 2–8°C | 32 | 44 | $P = 0.017$ |
| 4 | Unopened insulin can be stored at room temperature below 25°C | 14 | 34 | $P = 0.001$ |
| 5 | Premixed insulin should be mixed before injection | 13 | 30 | $P = 0.001$ |
| 6 | Insulin is absorbed most rapidly in the abdomen | 25 | 28 | NS |
| 7 | The shelf life of insulin used after opening should not exceed 4 weeks | 30 | 44 | $P = 0.001$ |
| 8 | The upper arm injection point can be selected from the side or the rear side | 25 | 35 | NS |
| 9 | Insulin should be carried with you when are going out | 31 | 43 | $P = 0.004$ |
| 10 | After insulin injection, the injection needle should be removed and discarded in the stab-proof medical garbage can | 35 | 45 | $P = 0.006$ |
| 11 | The injection point in the buttocks is the upper lateral part | 40 | 43 | NS |
| 12 | Insulin type and dose should be checked before injection | 11 | 38 | $P < 0.001$ |
| 13 | Check injection site and disinfect | 19 | 39 | $P < 0.001$ |
| 14 | The correct method of exhaust is to exhaust first and then adjust the injection dose | 20 | 40 | $P < 0.001$ |
| 15 | Know the correct way to install insulin needle | 36 | 41 | NS |
| 16 | Know the symptoms and manifestations of hypoglycaemia | 28 | 39 | $P = 0.014$ |
| 17 | The needle of insulin injection pen is disposable | 41 | 45 | NS |
| 18 | Insulin can be used for no more than 28 days after opening | 35 | 46 | $P = 0.002$ |
| 19 | Know your blood sugar control goals | 24 | 40 | $P < 0.001$ |

(continued)

**Table 2.** Continued.

| Question number | Question | Number of correct answers: Control group $n = 48$ | Number of correct answers: Observation group $n = 48$ | Statistical analyses[a] |
|---|---|---|---|---|
| 20 | Master the technique of injecting the insulin pen | 9 | 36 | $P < 0.001$ |

Data presented as *n* of patients.
[a]Categorical data were compared using $\chi^2$-test.
$HbA_{1c}$, glycosylated haemoglobin; NS, no significant between-group difference ($P \geq 0.05$).

**Table 3.** Comparison of the effects on blood glucose control of patients with diabetes mellitus that were enrolled in a study to investigate the clinical effect of improved insulin injection techniques in the treatment of diabetes mellitus under the guidance of continuous nursing.

| Characteristic | Control group $n = 48$ | Observation group $n = 48$ | Statistical analyses[a] |
|---|---|---|---|
| $HbA_{1c}$, % | $6.36 \pm 1.12$ | $5.87 \pm 1.04$ | $P = 0.030$ |
| FBG, mmol/l | $8.18 \pm 1.82$ | $7.34 \pm 1.67$ | $P = 0.017$ |
| 2-h PBG, mmol/l | $6.64 \pm 1.53$ | $5.68 \pm 1.42$ | $P = 0.002$ |
| Blood glucose target time, days | $3.87 \pm 1.04$ | $3.25 \pm 1.02$ | $P = 0.004$ |

Data presented as mean ± SD of all measurements for all participants in each group during the 6-month follow-up period.
[a]Continuous data were compared using Student's *t*-test.
$HbA_{1c}$, glycosylated haemoglobin; FBG, fasting blood glucose; 2-h PBG, 2-h postprandial blood glucose.

**Table 4.** Comparison of the occurrence of adverse events over a 6-month follow-up period after discharge of patients with diabetes mellitus that were enrolled in a study to investigate the clinical effect of improved insulin injection techniques in the treatment of diabetes mellitus under the guidance of continuous nursing.

| Adverse event | Control group $n = 48$ | Observation group $n = 48$ | Statistical analyses[a] |
|---|---|---|---|
| Subcutaneous mass | 10 (20.83) | 1 (25.00) | $P = 0.001$ |
| Insulin leakage | 12 (2.08) | 2 (4.17) | $P = 0.024$ |
| Hypoglycaemic event | 8 (16.67) | 1 (2.08) | $P = 0.001$ |
| Pain score | $6.54 \pm 1.57$ | $5.27 \pm 1.56$ | $P = 0.001$ |

Data presented as *n* of patients (%) or mean ± SD of all measurements for all participants in each group during the 6-month follow-up period.
[a]Continuous data were compared using Student's *t*-test and categorical data were compared using $\chi^2$-test.

implement personalized care for each patient.[26] At the same time, the nursing staff should pay attention to the mental health of patients with diabetes mellitus, set aside time for mental health education of patients every week, encourage patients' families to talk with patients about topics they are interested in, help patients relieve negative emotions, so that patients have a correct and scientific cognition of the disease.[27] After discharge, the patients should be visited and educated about their insulin injection status, daily diet and other aspects by telephone and email survey at regular

intervals.[28,29] On the basis of continuous care, this current randomized trial provided education and optimization of insulin injection techniques for patients in the observation group. The results showed that compared with the control group, the mastery of insulin injection technology in the observation group was significantly improved.

Although the efficacy of continuing care for the control of clinical disease remains unclear, continuing care combined with optimized insulin technology is postulated to play a positive role in the treatment of patients with diabetes mellitus. To test this hypothesis, this current randomized trial evaluated the efficacy of patients in terms of blood glucose changes, complication rates and other aspects of their diabetes management. Results showed that compared with the control group, continuous care combined with optimized insulin injection technology significantly reduced blood glucose target time, FBG, 2-h PBG and $HbA_{1c}$. In addition, the proportion of patients reporting a subcutaneous mass, insulin leakage and hypoglycaemic events during the 6-month observation period was significantly lower in the observation group. The pain scores were also significantly reduced in the observation group compared with the control group during the 6-month observation period.

As a chronic disease, the control of diabetes mellitus requires comprehensive care and an effective diabetes management programme may need to span multiple stages over an extremely long period of time.[30,31] With the popularity of health awareness, traditional nursing seems to be unable to meet modern standards for self-management, so a comprehensive continuity of care plan might be required to help patients control their blood glucose levels.[32] In recent years, continuous care has received more and more attention. To the best of our knowledge, no studies have examined the clinical effects of continuous care combined with optimized insulin injection techniques in patients with diabetes mellitus.

This current randomized trial had several limitations. First, the study consisted of a relatively small sample from a single institution. A more comprehensive study of a multi-institutional sample is necessary in the future to validate these findings. Secondly, the minimum sample size was not calculated statistically. Thus, the results may not be representative. In the future, a more favourable experimental basis for clinical research will need to be provided.

In conclusion, the findings of this randomized trial suggest that continuity of care, such as continued professional contact, may be an important part of managing diabetes mellitus in the long term. In future studies, the role of continuous care in other aspects of disease control will be explored.

## Author contributions

F.Y.Z. and M.S. conceived and proposed the idea. F.Y.Z. and L.Q.S. designed the work. M. S. and F.Y.Z. contributed to the interpretation of data. F.Y.Z. and L.Q.S. drafted the manuscript. M.S. revised it critically for important intellectual content. All authors made a significant contribution to the work reported, whether that was in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

## Declaration of conflicting interest

The authors declare that there are no conflicts of interest.

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## ORCID iD

Fang-Ying Zhang https://orcid.org/0000-0002-3344-1764

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