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## Original Research

# Exploring the process when developing a lifestyle intervention in primary care for type 2 diabetes: a longitudinal process evaluation



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## ABSTRACT

**Objectives:** A thorough understanding of the processes involved in lifestyle interventions is needed in order to close the gap between research and daily practice. This study explored the processes involved in the provision of a lifestyle intervention to patients with type 2 diabetes mellitus (T2DM) by health care professionals in primary care.

**Study design:** Mixed methods.

**Methods:** Health care professionals were asked to intensify lifestyle interventions for patients with T2DM in a routine care setting. Data were collected by serial interviews with health care professionals and patients, recorded consultations, an activity questionnaire and biomedical information. Qualitative data were analysed using a framework analysis with a phenomenological approach.

**Results:** The lifestyle intervention developed by the health care professionals included motivational interviewing, a nutrition and physical activity diary, and a multidisciplinary approach [physiotherapist, dietician, general practitioner and diabetes practice nurse (DPN)]. Participants and health care professionals were positive about the intervention, and patients were more active ( $P = 0.027$ ), lost weight ( $P = 0.031$ ) and had lower levels of glycated haemoglobin ( $P = 0.012$ ). However, qualitative data showed that patients were passive during the consultation, and did not ask questions about ways to improve their lifestyle. DPNs did not use motivational interviewing optimally; provided patients with information that was difficult to understand; and were easily satisfied with the efforts of the patients.

**Conclusions:** Lifestyle intervention for patients with T2DM is difficult in routine primary care. DPNs should adapt to the knowledge level of the patients, and patients must be stimulated to take an active role in their treatment. Patients and health care professionals should become equal partners in determining mutually agreeable treatment plans and goals.

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## Introduction

Lifestyle improvement is one of the most important components in the management of type 2 diabetes mellitus (T2DM),<sup>1</sup> and can have sustainable positive effects on weight and cardiovascular risk factors.<sup>2</sup> However, lifestyle interventions in primary care settings are not convincingly effective,<sup>3,4</sup> and the diabetes pandemic is ongoing.<sup>5</sup> To close the evidence gap between results from experimental settings and real-world practice,<sup>6,7</sup> research is needed to translate experimental interventions into effective and cost-effective real-world interventions. In addition, knowledge about current lifestyle management in daily practice is essential.

An important aspect of effective lifestyle support is patient–provider communication. In patients with diabetes, Ciechanowski et al.<sup>8</sup> found that the patient–provider relationship is very important for treatment adherence, and poor communication between the patient and the healthcare provider may have a negative effect on adherence. Other studies endorsed these results, and showed that diabetes management can be frustrating and may lead to feelings of incompetence for both patients and healthcare providers, which in turn impedes good diabetes management.<sup>9,10</sup>

To narrow the gap between results in the research setting and real-world practice, a thorough understanding of the communicative processes of lifestyle interventions in real-world practice is necessary. The aim of this study was to explore the process from the perspectives of the patient and the health care professional when health care professionals developed and implemented a real-world lifestyle intervention for patients with T2DM in primary care.

## Methods

### Setting

Primary care for T2DM is formalized in The Netherlands with diabetes management programmes (DMPs). Health care organizations formulate their own DMPs, but they generally consist of three quarterly consultations with a diabetes practice nurse (DPN) and one annual consultation with a general practitioner (GP). Patients can usually be referred to a dietician for one consultation, but exercise therapy is not a standard component. The regular consultations are mainly used to check diabetes-related biomedical markers, leaving very little time for lifestyle management.

In 2010, the authors asked two health care centres (HCCs) if they wished to set up a lifestyle intervention (without the authors' assistance), and explained that they wished to explore the process of developing and implementing this intervention, but did not intend to evaluate its effectiveness. HCCa, located in a semi-rural village, had four GPs, 386 registered patients with T2DM and 176 patients with impaired fasting glucose (IFG). Most of the patients had low socio-economic status and were middle-aged or older. HCCb, located in an urban neighbourhood in a small town, had two GPs, 218 registered patients with T2DM and four patients with IFG. The three DPNs at both HCCs were trained in motivational interviewing, but this training was not part of this study.

### Design

To avoid top-down implementation by the researchers, health care professionals developed a lifestyle intervention for patients with T2DM. The health care professionals designed the outline and content of the intervention in a brainstorming session. They discussed how they would ideally arrange lifestyle management within their knowledge, financial and practical possibilities, fitting into daily practice as much as possible.<sup>11</sup> Difficulties when providing lifestyle interventions were identified and discussed. The researchers did not interfere with the content of the intervention. Quality improvement interventions were executed as designed by the health care professionals, and evaluated throughout the intervention period using longitudinal process evaluation.<sup>12</sup>

### Recruitment and sampling

Patients were approached by their GP or DPN and received information about the lifestyle intervention and the process evaluation. A heterogeneous study population was recruited using purposive sampling. All patients aged >18 years with T2DM or IFG, without a life-threatening physical illness or severe mental disorder, were eligible to participate in the intervention. All patients gave written informed consent. The Medical Ethical Committee of Maastricht University granted ethical approval.

### Data collection

A blueprint was developed to determine which data should be collected for the process evaluation (Table 1).<sup>12,13</sup> The process evaluation consisted of the following components: structure and content of the intervention; delivery and implementation; experiences of patients and health care professionals; observed effects of the intervention; and important processes during consultations.

A considerable amount of data, including follow-up data, was required in order to explore the barriers longitudinally. As such, the authors aimed to recruit a small number of participants and perform serial collection of both qualitative and quantitative data.<sup>11</sup> Patient consultations with health care professionals provided data for the evaluation. In addition, serial interviews<sup>14,15</sup> were held with patients (CvR, JL) and group interviews were held with health care professionals (CvR, JL). A physical activity questionnaire (baseline and after intervention) was completed and biomedical data (baseline and after intervention) were collected. All consultations and interviews were audio recorded and transcribed for analysis.

Patient interviews were conducted after each consultation with a GP or DPN. Group interviews with the professionals were conducted before (in the brainstorming session) and after the intervention. A semi-structured open-ended interview guide (Table 2) was developed for the interviews. Quantitative outcome measurements consisted of sociodemographic (age, gender, duration of T2DM) and biomedical data [glycated haemoglobin (HbA1c), blood pressure, cholesterol, body mass index (BMI), fasting blood glucose, waist circumference]. Data on physical

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