**Title page**

*"Hypoglycemia in older people with diabetes receiving home care. A feasibility-study".*

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# Abstract

*Background*

Hypoglycemic incidents in older people can cause severe health problems, enhance general age-related disabilities and cause frailty. Little is known about incidence of hypoglycemia in older home-dwelling people with diabetes. Thus, the aim of this study was to investigate the feasibility of using continuous glucose monitoring (CGM) and standardized questionnaires on issues associated with increased risk of hypoglycemia among older home dwelling individuals with diabetes type 2 receiving home care.

*Methods*

CGM with the Ipro2 blinded monitoring system were performed for five days in six home-dwelling individuals ≥ 75 years diagnosed with diabetes and receiving home care. Demographic (age, gender, living arrangements) and clinical data (diabetes diagnoses and duration, diabetes medication, documented treatment goal, available glycosylated hemoglobin (HbA1c),) were collected from electronic patient records in home care services. Feasibility (ease of use, quality of data, time spent) of standardized questionnaires to identify the risk of hypoglycemia (the McKellar Risk Assessment Tool), risk of malnutrition (the Mini Nutritional Assessment (MNA)), functional status (the Individual-based Statistics for Nursing and Care Services (IPLOS)) and cognitive status (the Mini Mental Status Exam (MMSE)) was also assessed. Questionnaire data were collected by a study nurse in the individuals' home.

*Results*

The practical use of CGM was satisfactory, with no major remarks about discomfort or technical errors, except for one participant with skin reaction (redness). Collecting data with

the McKellar Risk Assessment Tool, MNA and IPLOS worked well according to quality of data, time spent and ease of use. The MMSE survey required extensive training of personnel to be conducted.

*Conclusion*

The feasibility study inform  an upcoming study on the incidence and risk factors of hypoglycemia in home dwelling older individuals, were we will reconsider the use of the MMSE questionnaire.  The use of blinded CGM in this population was well tolerated and can be used ‘as is’ for future studies.

*Keywords*

Diabetes, hypoglycemia, older people, HbA1c, home care.

## Background

As a consequence of increased wealth, better treatment and rapid development of treatment aids people with diabetes live longer (1). The prevalence of diabetes in older people > 65 years has been estimated to reach 17. 9% by 2045 according to the IDF Diabetes Atlas (2). In individuals receiving home care, a recent study conducted in Norway revealed a prevalence of 24% diabetes (3, 4). Several studies have shown that a substantial proportion of older people are overly intensified treated with an HbA1c lower than recommended in guidelines for older people with diabetes (5-7). This can increase risk of hypoglycemia in older people treated with insulin or insulin secretagogues drugs. However, these drugs are vital to maintain adequate blood glucose control, and to prevent diabetes related comorbidity and complications.

Hypoglycemic incidents in older people can cause severe health problems, enhance general age-related disabilities and cause frailty (8). Hypoglycemia among older people with diabetes is associated with a number of negative outcomes like vascular complications, cognitive dysfunction, risk of fall and fractures and coma and death (9, 10). In addition, response to hypoglycemia is impaired due to altered adaptive physiological response to low glucose levels in older people. Thus, older home-dwelling people with diabetes are a vulnerable group representing a challenge for home care services.

Health care personnel has an important task in the matter of securing patients with diabetes against unfortunate events in the home and prevent hypoglycemia. WHO has defined patient safety as “prevention of errors and adverse effects to patients associated with health care” (11). According to a recent literature review, there seems to be a gap between knowledge and understanding of patient safety and the risk of adverse events (12). The paper identified

several interactive domains as a tool for systematic reviewing of services and to point out improvement areas. For diabetes patients living at home receiving secure health care entail that the health care personnel are able to identify symptoms to be able to take action.

Studies reporting on hypoglycemic incidents in older people with diabetes are often based on severe hypoglycemia in hospitalized patients and does not describe the situation in a home dwelling older population with diabetes (13-16). In line with this, we have designed an observational study to investigate the feasibility of continuous glucose monitoring (CGM) and use of standardized questionnaires on issues associated with increased risk of hypoglycemia among older home-dwelling individuals ≥ 75 years with diabetes type 2 receiving home care. The findings of the present feasibility study will inform a larger observational study scheduled to autumn 2020.

## Methods

*AIM*

The overall aim of the present study was to examine the feasibility of capturing hypoglycemia and issues associated with increased risk of hypoglycemia by use of CGM and standardized questionnaires among older home-dwelling individuals ≥ 75 years with diabetes type 2 receiving home care.

We proposed the following research questions:

1. To what extent is the CGM Ipro2 system, suitable for detecting occurrence of hypoglycemia in home-dwelling individuals ≥ 75 years with diabetes type 2 receiving home care?

2. To what extent are standardized questionnaires suitable for evaluating issues associated with increased risk of hypoglycemia, risk of malnutrition, level of functioning and cognitive status in this study population?
3. To what extent are study procedures on collecting demographic, clinical, CGM and questionnaire data suitable to study hypoglycemia in older people receiving home care with respect to ease for the individuals and health care professionals, quality of the data and appropriateness of the data format for further processing?

*Design*

We used a feasibility study design to examine study procedures, as well as measures and instruments to be used in an upcoming larger observational study. The study does not focus on the outcome of the data itself (14).

*Setting and participants*

We conducted the study in a small municipality in Eastern Norway during seven weeks in November and December in 2018. We identified all older home-dwelling individuals ≥ 75 years diagnosed with diabetes type 2, treated with insulin and/or sulfonylurea and receiving home care. We identified eligible participants from the home care electronic patient records. Home care nurses gave oral and written information and invited eligible participants to take part in the study. All participants signed a written consent form. People who were unable to complete questionnaire data were excluded. Furthermore, we did not invite patients with severe cognitive deficiency (e.g. Alzheimer disease), severe medical comorbidity (e.g. end stage renal disease, severe heart failure, severe cancer), and/or a major psychiatric diagnosis (e.g. severe depression or bipolar disorder, schizophrenia) recorded in their medical records.

*Data collection*

Sociodemographic and clinical data from electronic patient records on date of birth, sex, height/weight, living arrangement (living with others, living alone), diabetes duration, diabetes medication (insulin and/or sulfonylurea), documented treatment goal (glycosylated hemoglobin (HbA1c)) (yes/no), frequency of HbA1c measuring and type and incidence of adverse events. We developed a case report form for collecting these data.

The two study nurses assisted by the first author (ABL) collected blood glucose data by connecting the CGM in the patients' home. We used the CGM Ipro2 system, a blinded glucose monitor. The Ipro2 monitor is a "silent" measuring tool which requires capillary blood glucose samples for calibration. For each participant, CGM data were collected for five consecutive days. In addition, capillary blood tests were performed three times daily during the five days either by the patient themselves or with help from the home care nurse when necessary. The study nurses provided training for those participants who were able to fill in the meal diary and blood glucose measurement forms themselves.

We gathered data on practical issues in filling in questionnaires during home care visits, observed participants' ability to complete the instruments and recorded time and need of resources. We also wrote down individual feedback from the participants who commented on the procedures, as well as the included items and scales within the instruments. We used the following standardized instruments to collect questionnaire data on 1) risk of hypoglycemia (the McKellar Risk Assessment Tool), 2) risk of malnutrition (the Mini Nutritional Assessment (MNA) scale), 3) level of functioning (the Individual-based Statistics for Nursing and Care Services (IPLOS)), and 4) cognitive status (the Mini Mental State Exam (MMSE)).

Questionnaire data were collected on day 1 and 5 combining the connection and disconnection of the CGM sensor to save time.

*The McKellar Risk Assessment Tool* (17) represent questions about issues associated with increased risk factors on hypoglycemia; recognizing symptoms, mental state, treatment goals (HbA1c < 53), treatment (insulin/sulfonylurea), kidney or liver disease, recent episode, other medication and nutrition (17). *The Mini Nutritional Assessment scale* (MNA) (18) assesses the risk of malnutrition and is divided into two sections of questions, one short section (A-F) with a total score of 14 points were < 11 points constitutes "risk of malnutrition" and < 7 points is "malnutrition" (18). Section two (G-R) gives an in-depth assessment to point out improvement areas with a total score of 16 points, a total score of 30 points all together. *Individual-based Statistics for Nursing and Care Services* (IPLOS) (19) focus on the individual´s level of functioning in interaction with the surroundings and are used in home care on a regular bases in Norwegian municipalities to verify need of assistance (19). The variables are based on the International Classification and Functioning, Disability and Health (ICF) manual and represents different degrees of disability from 1. "no problems" to 5. "not able to". *The Mini Mental State Exam* (MMSE) (20) is a diagnostic tool for cognitive status, impairment and dementia (20). It is divided into six eras of cognitive skills, each question derived 0 or 1 point.

*Analysis*

We applied descriptive statistics for demographic and clinical data, number of invited participants and number and percentage of people who agreed to participate. For CGM data Time-In-Range (TIR) was defined between 3.9 and 8.3 mmol/l in this feasibility study. We calculated percentage of total time in TIR for each individual. Furthermore, we calculated

total score for each individual as well as range of scores, for all questionnaire scales. For *The McKellar Risk Assessment Tool* (17) the total score is 12 were only one risk factor evaluates to “high risk of hypoglycemia”, two or more gives “very high risk of hypoglycemia”. *The Mini Nutritional Assessment scale* (MNA) (18) gives a maximum score of 30 points which indicates a “normal nutrition status”, < 24 points “risk of malnutrition” and < 17 “malnutrition”. *The Individual-based Statistics for Nursing and Care Services* (IPLOS) (19) indicates a need for assistance if the if the score exceeds 3 points (19). *The Mini Mental State Exam* (MMSE) (20) has a maximum score of 30 points. Normal functioning is 28-30 points, 25-27 points indicates cognitive impairment, 24 points or less indicates cognitive failure, but further investigations are needed.

## Results

*Recruitment*

In this small municipality, we identified 20 patients with diabetes type 2 of whom 12 were men and 8 women. Eleven of them did not meet the age inclusion criterion so we asked 9 eligible patients to participate. Two of them did not want to participate due to severe illness (cancer, mental illness) and one felt bound and stressed by the thought of having different people from home care entering their home several times a day. Finally, six participants agreed to participate (Figure 1).

*(Insert Figure 1. here).*

*Feasibility for collecting sociodemographic and clinical data*

We collected data from EPJ in home care on sociodemographic and clinical data and treatment goal (HbA1c). Complete sociodemographic and clinical data were available for all

patients. Lack of data was identified for HbA1c. The case report forms for collecting sociodemographic and clinical data, meal diary and blood sugar measurements worked fine.

*Sample characteristics*

The participants had a mean duration of diabetes of 20 years and a mean age of 83 years (Table 1). Three persons lived alone. All persons were treated with insulin and or other glucose-lowering medication. Height range was 169-187 cm and weight range was 72-94 kg.

*Table 1. Sociodemographic and clinical data in older people (≥75) with diabetes receiving home care (n=6).*

| | **Person 1** | **Person 2** | **Person 3** | **Person 4** | **Person 5** | **Person 6** |
|---|---|---|---|---|---|---|
| Birth | 1935 | 1930 | 1943 | 1931 | 1937 | 1943 |
| Gender | Male | Female | Male | Female | Male | Male |
| Hight/cm | 174 | 175 | 180 | 169 | 187 | 176 |
| Weight/kg | 93 | 76 | 88 | 72 | 94 | 74 |
| Living arrangement | Living with others | Living alone | Living with others | Living alone | Living with others | Living alone |
| Diabetes duration | 25 years | 18 years | >20 years | >15 years | 15 years | 18 years |
| Diabetes treatment | Insulin | Insulin Linagliptin Metformin | Insulin Linagliptin | Insulin Linagliptin | Insulin Linagliptin Glimepirid Dapagliflozin | Insulin Metformin |

*Feasibility for CGM*

The use of CGM among older home-dwelling people with diabetes was feasible. All patients completed all five days CGM measurement. Regarding practical use of CGM, one patient reported skin reaction (redness) and none reported pain. Furthermore, there were no technical errors, except for one sensor that fell off. Thus, the registration for this individual was delayed with one week. Daily finger tests were used to calibrate the sensor and worked fine without any special challenge. All individuals performed three measurements of capillary blood glucose daily, three of them had help from home care nurses who performed the tests.

Downloading data to CareLink was time consuming due to compatibility problems with more recent drivers.

*Occurrence of hypoglycemia data*

Regarding the CGM measurements we collected 945-1140 sensor values between 3 and 22.2 mmol/L. TIR (3.9-8.3 mmol/L) varied between 0- 63 %. In three individuals, blood glucose values were < 3.9 mmol / l, i.e. hypoglycemic episodes, with a duration of between 15-50 minutes (Table 2).

*Table 2. Continuous Glucose Measure values in older people (≥75 years) with diabetes receiving home care (n=6).*

| | **Person 1** | **Person 2** | **Person 3** | **Person 4** | **Person 5** | **Person 6** |
|---|---|---|---|---|---|---|
| Sensor values (n) | 1126 | 1091 | 1154 | 1138 | 1148 | 945 |
| Highest (mmol/L) | 19.4 | 12.5 | 22.2 | 18.4 | 21.8 | 22.2 |
| Lowest (mmol/L) | 6.8 | 3 | 5.7 | 8.3 | 3.5 | 3.1 |
| Average (mmol/L ± SD) | 11.7±2.8 | 7.7±1.8 | 14.1±3.6 | 13 ±1.7 | 9.2 + 2.9 | 14.1±4.5 |
| % within TIR[1] | 10 | 63 | 7 | 0 | 45 | 9 |
| % over 8,3 mmol/L | 90 | 37 | 93 | 100 | 55 | 89 |
| Under 3.9 mmol/L (n) | 0 | 1 | 0 | 0 | 1 | 2 |
| Duration under 3.9 mmol/L (min) | 0 | 0:25 | 0 | 0 | 0:15 | 0:25/0:50 |

[1]Time-In-Range

*Feasibility for questionnaires*

Collecting questionnaire data during day 1 and 5 of the CGM period by two study nurses, assisted by the first author, was feasible. All patients completed the questionnaires. Some had difficulties to understand the meaning of some of the questions and we had to elaborate. As we assisted the patients in filling in the questionnaires some people with hearing impairment had more difficulties that made the data collection more time consuming. Median range of time on each visit was 20 to 62 minutes on visit one and from 31 to 62 minutes on visit

number two (Figure 2). Regarding practical use of the MNA scale and IPLOS, interview manuals were used to support the questionnaire (available online) (18, 19, 21). The protocol initially contained four questionnaires, but the MMSE required extensive skills and training among home care personnel and could therefore not be performed.

*(Insert Figure 2. here)*

*Risk of hypoglycemia, malnutrition and level of functioning*

The McKellar Risk Assessment tool was suitable to identify factors associated with hypoglycemia. All six individuals were at "very high risk of hypoglycemia" due to risk factors like kidney disease, stroke, swallow palsy, diarrhea, insulin treatment (n=5) and combination of insulin and sulfonylurea (n=1) in addition to polypharmacy (n=6). One person recently had a hypoglycemic event which required assistance. Regarding the McKellar risk survey, four out of six said that they did not notice any symptoms of hypoglycemia. Correspondingly, CGM measurements identified episodes of low blood glucose < 3.9 mmol/L in three of these four persons that did not notice any symptoms during the five days of data collection. In this questionnaire, one out of six reported HbA1c < 53 mmol/mmol and four out of six did not know their HbA1c level.

The Mini Nutrition Assessment was suitable to identify risk of malnutrition (Figure 3). Four out of six persons had risk of malnutrition (score 17-23 points). Some persons had difficulty swallowing, others had a physical dysfunction caused by stroke, poor appetite from depression, esophageal hernia and diarrhea and some forgot to eat because of their impaired cognitive functioning.

*(Insert Figure 3. here)*

The Individual-based Statistics for Nursing and Care Services (IPLOS) was able to identify areas in physical dysfunctioning. The most common dysfunction areas were “common housekeeping”, “self-care” and “moving outdoors” (Figure 4). Common housekeeping gave the highest scores between 3-5 on (black) scale. Self-care (grey column) is the second highest score and several persons had disabilities (amputation of leg, leg wound, cognitive impairment/dementia) and were in need of medical attention and assistance. Third (shaded column) was moving outside which was difficult for all of them without the use of aids and assistance from others.

*(Insert Figure 4. here)*

## Discussion

The use of CGM Ipro2 system to detect hypoglycemia and the use of standardized questionnaires collecting data on self-reported hypoglycemia, nutrition status and functional status was feasible. Older home-dwelling people were willing to participate and found the study procedures acceptable. The results indicate that CGM is well suited to disclose the frequency and occurrence of asymptomatic hypoglycemia in older home-dwelling people with diabetes receiving home care. The practical use of the McKellar tool, the MNA and IPLOS assessment worked well in the home care environment. However, using the MMSE was more challenging because of the requirement of trained personnel.

In research studies the Ipro2 is used for blinded continuous glucose monitoring, as it does not have alarms and warnings to avoid hypoglycemia so that the person can make decisions to ingest carbohydrates before an incident occurs (22). Otherwise, in real monitoring the

warnings will serve as counterbalance to avoid severe hypoglycemia and home care personnel will receive digital information and be able to provide help. There are several studies which confirms that CGM is appropriate in monitoring the occurrence of asymptomatic hypoglycemia (22, 23). However, the use of CGM should be discussed in home care, as the technology identifies the occurrence of hypoglycemia that need to be acted upon. This feasibility study has identified practical and technical aspects important for a larger observational study using CGM among groups of home-dwelling older individuals receiving home care using insulin of other glucose lowering drugs. Nevertheless, there is a question of cost, disturbing alarms, practical use and training that must be taken into consideration.

In previous research it has been shown that hypoglycemic unawareness is highly prevalent in older adults and a common cause of silent hypoglycemia (9). In this feasibility study, TIR was 10 % or less in four of six participants. Moreover, insufficient diabetes management and large blood glucose fluctuations were detected in all six participants. Three participants had blood glucose values < 3.9 mmol/l between 15-34 minutes that they could not account for. These findings corresponds to previous knowledge about failing insulin production in response to glucose intake and insufficient physiological responsiveness with older age (24). Postprandial hyperglycemia in connection with meals has shown values > 11 mmol/l measured two hours after intake and therefore cause large blood sugar fluctuations. In response to hyperglycemia our participants had short-acting insulin (n=6) and sulfonylurea (n=1) to compensate for and/or correcting their blood glucose rising > 12 or 15 or 20 mmol/L according to electronic patient records.

Availability of study nurses during data collection was essential, as the participants needed some guidance to complete the questionnaires. Time spent in home visits was higher if the

person had hearing problems and cognitive impairment. Using a clear voice, being well prepared, keep eye contact and act calmly were important to build trust and minimize time spent. Collection of questionnaire data during home visits were the person lived together with a partner was also more time consuming. Regardless, the partner provided good support and helped to create a safe atmosphere. To inform the main study, all questionnaires were feasible except for MMSE. This instrument demands more comprehensive training for study nurses to be able to perform. A recent review article highlights the gap between knowledge and understanding of safety for older people with diabetes in a home care setting (12, 25). The McKellar risk assessment tool identified three instances of hypoglycemia unawareness that can lead to serious complications and decreased safety, especially for those living alone.

Providing proper information about the study to all parties involved should be emphasized to optimize planning, procedures and efficiency of measures. For two participants, a general practitioner had to be consulted to reconsider the dose of blood glucose lowering medication. Therefore, to avoid misunderstandings and unnecessary time spent, formal collaboration with the participants' general practitioners need to be established in the main study.

Insufficient diabetes management routines in regard to regular assessment of HbA1c in electronic patient records were identified. However, previous research has identified that a substantial proportion of older people are too intensively treated with an HbA1c lower than recommended in guidelines for older people with diabetes (3, 5-7). This can increase risk of hypoglycemia in older patients treated with insulin or insulin secretagogues drugs. Therefore, in the main observational study this issue has to be addressed in order to gain valid information on fulfillment of treatment goal in accordance with guidelines for older people with diabetes. Optimal care requires correct and updated information about treatment goals

(HbA1c) in addition to daily blood tests. Health care personnel must be able to make accurate decisions about insulin dosages and recognize diabetes-related symptoms and actions.

*Strengths and limitations*

This study was conducted in only one smaller municipality with a limited number of participants (n=6) which might differ from the variability among communities in the full scale study. Moreover, the study included only people using insulin and it gave no comparison to other diabetes treatments. Still, we included both genders and both persons who live alone and those with cohabitants. It might be considered a strength that the study nurses knew all participants which made the participants feel safe and well cared for. However, such close relations might also influence their answers to the questionnaires e.g they might appear more compliant regarding treatment and diet.

## Conclusion

The feasibility study informs an upcoming study on the incidence and risk factors of hypoglycemia in home dwelling older individuals with diabetes, were we will reconsider the use of the MMSE questionnaire. The use of blinded CGM in this population was well tolerated and can be used ‘as is’ for future studies.

**List of abbreviations**

CGM - Continuous Glucose Monitoring

EPJ – Electronic Patient Journal

MNA – Mini Nutritional Assessment

MMSE – Mini Mental Status Exam

IPLOS - Individual-based Statistics for Nursing and Care Services

ABL – Annette Bævre Larsen

HbA1c – glycated haemoglobin

TIR – Time-In-Range

## Declarations

*Ethical approval and consent to participate*

The study was approved by the South-East Norway Regional Committee for Medical and Health Research Ethics (REK no. 2018/512). The study was conducted according to the Helsinki declaration and written consent was obtained. Patients were informed about their ability to withdraw from the study at any time.

*Consent for publication*

Not applicable.

*Availability for data and materials*

The datasets generated during the current study are available from the corresponding author on reasonable request.

*Competing interests*

The authors declare that they have no competing interests.

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*Authors' contributions*

MG and MH designed the study. ABL coordinated the data collection. ABL drafted the manuscript. ABL, MH and MG revised the manuscript. All authors read and approved the final manuscript.

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