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Study protocol for assessing the user acceptance, safety and efficacy of a tablet-based workflow and decision support system with incorporated basal insulin algorithm for glycaemic management in participants with type 2 diabetes receiving home health care: A single-centre, open-label, uncontrolled proof-of-concept study

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ABSTRACT

Introduction: Diabetes management can be especially complex for older adults who receive health care at home. Thus, international guidelines recommend basal-insulin regimens due to simpler handling and low hypoglycaemia risk. A basal-insulin algorithm (including basal-plus) was developed to also include participant's health status and subsequently implemented into a tablet-based workflow and decision support system, GlucoTab@MobileCare. This study protocol describes a proof-of-concept study to investigate user acceptance, safety and efficacy of the GlucoTab@MobileCare system in participants receiving home health care.
Methods: The open-label, single-centre, uncontrolled study will recruit a maximum of ten participants with insulin treated type-2-diabetes (age ≥18 years) who receive home health care. During a three month study period participants will receive basal- or basal-plus-insulin therapy once daily as suggested by the GlucoTab@MobileCare system. Statistical analysis will be conducted on an intention-to-treat basis. The primary endpoint is the percentage of tasks (BG measurements, insulin dose calculations, insulin injections) that were performed according to GlucoTab@MobileCare suggestions relative to the total of suggested tasks. Secondary endpoints include user acceptance, safety and efficacy parameters. The study was approved by the ethics committee and regulatory authorities. Before obtaining written informed consent, all participants will receive oral and written information about all aspects of the study. Results will be published in a peer-reviewed journal and at diabetes and geriatric conferences.
Discussion: Potential implications may be improved quality and safety of basal-insulin therapy in older adults as well as support for health-care-providers in daily routine including evidence-based knowledge.
Trial registration: German Clinical Trials Register (DRKS00015059);

1. Introduction

One in four people aged 70 years or older suffers from type 2 diabetes [1–3]. The number of elderly people with diabetes is expected to rise worldwide from 123 million in 2017 to 253 million in 2045 [4] in the coming decades [5–7].

Diabetes can be a very complex disease in older adults, as they show higher mortality, are more likely to get institutionalised and have a

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greater risk for multiple comorbidities [8,9], such as coronary artery disease, heart failure, renal and liver disease, dementia, and increasing risk of hypoglycaemia [10]. Furthermore, elderly people with diabetes are more affected by several geriatric syndromes [8,9]. To maximise the quality of life for elderly people, diabetes management and an optimal treatment of type 2 diabetes must take into account not only medical, but also psychological, functional, and social geriatric aspects in people as they age [8].

Health care systems and professionals are challenged to provide high quality diabetes care for older people [11,12]. Special attention should be paid to home health care which supports people to improve functional status, to promote quality of life and to prevent institutionalisation [13]. Previous studies in several different countries have all shown that a large number of people with diabetes receive home health care: 30% in the United States [14], 27% in Germany [15] and 24% in Norway [16]. No actual prevalence data is available for Austria, but similar numbers can be expected.

International diabetes guidelines [8,10,17] highlight the importance of simplifying diabetes therapy strategies. This simplification can have an important positive impact on public health, as unnecessary hospitalisations and emergency department visits can be reduced. In addition it may contribute to maintaining the persons' overall health status [18]. Guidelines recommend a diabetes therapy regime that is as simple as possible [1] and has a low hypoglycaemic risk for older adults with type 2 diabetes [8]. Long acting basal insulins are the methods of choice [9–11,17,19–21], as they are simple to handle (e.g. pre-filled pen, injection only once daily) and bear a low risk of hypoglycaemia [22].

In cooperation with the Geriatric Health Centres of the City of Graz (GGZ), the Medical University of Graz (MUG) and JOANNEUM RESEARCH Forschungsgesellschaft mbH (JR) have developed a basal and basal-plus insulin algorithm based on guideline recommendations [10,23] and on geriatric health care professionals' expertise. The basal insulin algorithm considering the individual's health status has been incorporated into a tablet-based workflow and decision support system, which has been further developed for the home health care setting (GlucoTab@MobileCare) (Figs. 1–2).

This study protocol describes a proof-of-concept study to investigate user acceptance, safety and efficacy of the GlucoTab@MobileCare system for glycaemic management in participants with type 2 diabetes receiving home health care.

2. Materials and methods

2.1. Overview

The study is an open-label, single-centre, uncontrolled proof-of-concept study. Study participants will be adults aged 18 years or older with insulin dependent type 2 diabetes who receive home health care by the AUSTRIAN RED CROSS Graz. During a three months study period, participants will receive basal or basal-plus insulin therapy once daily as suggested by the basal insulin algorithm incorporated into Gluco-Tab@MobileCare. Ten participants are planned to be recruited. Methods for recruitment will comply with applicable regulatory documents and adhere to the ICH GCP guideline and to the requirements in the Declaration of Helsinki. Oral and written informed consent will be obtained from all participants before any study related activities. The study will be coordinated and conducted by the Division of Endocrinology and Diabetology (MUG) in cooperation with the JR and the AUSTRIAN RED CROSS Graz. Investigators will be study physicians employed at the diabetes outpatient clinic (MUG).

2.2. Inclusion criteria

- Informed written consent obtained after being advised of the nature of the study
- Male or female aged ≥18 years
- Type 2 diabetes (treated with insulin therapy)
- Receiving home health care by the AUSTRIAN RED CROSS Graz

2.3. Exclusion criteria

- Instable corticosteroid therapy
- Any disease or condition which the investigator feels would interfere with the study or the safety of the participant
- Any mental condition rendering the participant incapable of giving his/her consent
- Intravenous insulin therapy
- Hyperglycaemic episodes (ketoacidosis, hyperosmolar state) if they require intravenous insulin therapy
- Pregnancy
- Known or suspected allergy to certain insulin types
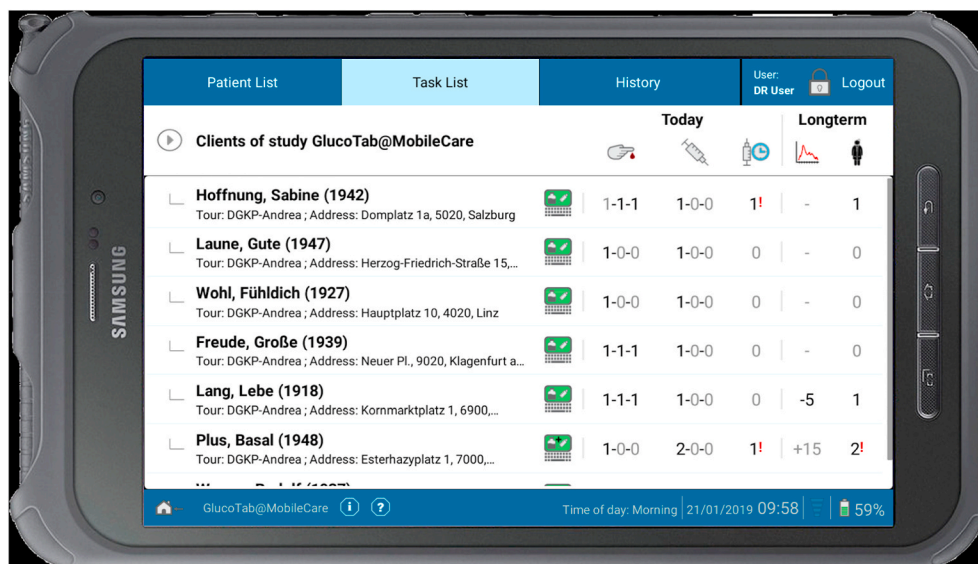- Terminally ill participants
- Total parenteral nutrition

Fig. 1. GlucoTab@MobileCare mock-up tasklist

Fig. 2. GlucoTab@MobileCare mock-up participant details.

• Participation in another study which could influence the basal insulin algorithm

2.4. GlucoTab@MobileCare

The basal insulin algorithm incorporated in the GlucoTab@MobileCare system (Figs. 1–2) supports health care professionals with the decision on which basal insulin dose to start with, when to adjust basal insulin dose, how much correctional insulin to administer if very high blood glucose (BG) values occur, and recommends an adequate BG measurement frequency according to health status and to previous BG levels. The algorithm has been incorporated in the GlucoTab® software to reduce user workload and increase safety by preventing users from having to calculate doses etc. themselves. This basal insulin algorithm is assumed to be safer, more flexible and less complex than standard diabetes care [11,20,22]. People who are treated with this algorithm are expected to experience less hypoglycaemic events and require less BG measurements compared to standard care.

The GlucoTab@MobileCare system is a client-server software system that consists of a mobile, tablet-based client and a backend server. The client acts as a user interface and communicates with the server via a mobile network.

The GlucoTab@MobileCare system provides two main functionalities for health care professionals:

1) Supporting healthcare professionals in managing the treatment workflow for participants with type 2 diabetes requiring home health care by providing
   a) automated workflow support which includes reminders for open tasks,
   b) facilitated ordering of glucose-lowering medication and documentation of medication administration as well as other parameters relevant for diabetes
   c) and visualization of BG, medication and nutrition.
2) Supporting subcutaneous basal insulin therapy, especially tailored to participants, by providing:
   a) insulin dose recommendations for an initial basal insulin dose and basal insulin titration support based on previous BG values and insulin doses. An authorised healthcare professional must confirm the suggested insulin dose in regular intervals.

b) workflow support for varying intensity of BG measurements (full daily profile during therapy initialisation phase versus fasting values only for ongoing therapy).
c) workflow support and dose calculation for basal-plus therapy which means administration of a short acting insulin with a defined meal.

At any time health care professionals can decide to take additional BG measurements and/or overrule the decisions suggested by the GlucoTab@MobileCare system in case a suggestion seems implausible and could possibly endanger the participant's health.

GlucoTab@MobileCare does not perform checks related to drug interactions. Other antidiabetic medications apart from insulin therapy, such as oral antidiabetic drugs (OAD), can be maintained by the physician's discretion during the study period. However, the basal insulin titration protocol may not be used in combination with glinides and/or sulfonylurea in order to avoid hypoglycaemia. GlucoTab@MobileCare does not automatically reduce/adjust insulin dose suggestions in case of changes in OADs. These factors must be considered by health care professionals.

User trainings with the GlucoTab@MobileCare system will be performed before study start to guarantee a safe implementation. For a detailed description of handling instructions, printed user manuals will be available at each AUSTRIAN RED CROSS site.

2.5. Study medication

Study medication will be basal insulin glargine U300, Toujeo® Solostar® therapy, following the basal insulin algorithm incorporated in the GlucoTab@MobileCare system, combined with or without OADs. BG corrections with short acting insulin for very high BG values (tight/moderate glycaemic control ≥ 16.7 mmol/L; loose glycaemic control ≥ 19.4 mmol/L) will be performed using insulin glulisine Apidra® Solostar®.

3. Study schedule

The study will consist of 4 study visits (Table 1).

Study visit 1 (recruitment visit) and study visit 4 (closing visit) will be conducted at the participant's home by the investigators. Study visits 2 and 3 (safety visits) will be conducted four and eight weeks after study start either by telephone or on-site visit by the investigators,

Table 1
Schedule of study visits.

Study visit number	1	2	3	4
Study visit name	Recruit-ment visit	Safety visit 1 (after 4 weeks)	Safety visit 2 (after 8 weeks)	Closing visit (after 3 months)
Informed consent	X			
In/exclusion criteria	X			
Demography (age, sex, ethnicity)	X			
Pregnancy test (for women of childbearing age)	X	X	X	X
Care dependency	X			X
Medical diagnoses	X			
Withdrawal criteria		X	X	
Body measurements (body weight, height, BMI)	X			
Vital signs (blood pressure, pulse)	X			X
Routine laboratory assessment (creatinine, GFR, HbA1c)	X			X
Blood glucose (capillary)	X	X	X	X
Adverse Events		X	X	
Concomitant medication	X	X	X	X
Diabetes therapy	X	X	X	X
Diabetes therapy at therapy start	X			
Glycaemic target range (health status)	X	X	X	
Home care nurse user acceptance parameters (questionnaire)	X			X
Participant/relative user acceptance parameters				X
End of study				X

respectively. Follow-up visits are not intended to be performed in this study.

3.1. Study period

Therapy start: Before obtaining written informed consent, all participants will receive oral and written information about all aspects of the study. When inclusion and exclusion criteria are met, the insulin start therapy will be ordered by the investigator. The investigator also evaluates OADs and decides whether to continue or stop OADs. Insulin therapy with basal insulin (Toujeo® Solostar®) will be initiated and adjusted according to GlucoTab@MobileCare suggestions. The initial basal insulin starting dose will be calculated as follows:

- ≥ 50 kg: 0.2 units/kg/day
- < 50 kg: 0.1 units/kg/day [10,23] or
- starting dose as judged by investigator.

Glycaemic target range of the algorithm: The goal of the basal insulin algorithm is to maintain fasting BG (FBG) within the FBG target range according to the predefined health status (e.g. number of comorbidities, care dependency, life expectancy, …) [8,24,25]:

- Healthy: FBG target 5.0–7.2 mmol/L,
- Complex: FBG target 5.0–8.3 mmol/L,
- Poor: FBG target 5.6–10.0 mmol/L.

To ensure that basal insulin is the most suitable therapy form, BG values should not rise by more than 8.3 mmol/L throughout the day compared to the FBGs assessed during the run-in period (see section BG measurements). After therapy start, basal insulin will be administered once daily in the morning.

Insulin dose titration: Insulin dose calculation will be performed following GlucoTab@MobileCare suggestions under supervision of the AUSTRIAN RED CROSS home care nurses. The basal insulin dose will be reduced by 2 units if any BG value is < 1.1 mmol/L below target and by 4 units if any BG value is > 1.1 mmol/L below target. The basal insulin dose will be increased according to a titration table. If participants also receive basal-plus insulin therapy, the bolus insulin component will be estimated initially with 20% of the basal insulin dose. If necessary, investigators can be contacted and will review the GlucoTab@MobileCare suggestion for correctness and plausibility.

BG measurements: For capillary BG measurements, routine standard devices will be used (AccuChek® Guide, Roche Diabetes Care). Capillary BG will be measured by home care nurses three times daily before each meal for at least the first three days of the basal insulin algorithm therapy. BG measurements will be done only once daily in the morning when basal insulin therapy has proven to be the suitable therapy (when BG values don't rise by more than 8.3 mmol/L compared to the FBG). For long-term treatment, GlucoTab@MobileCare will suggest three pre-meal BG measurements once a month on a single day.

All capillary BG measurements and insulin dosing will be performed and documented in the GlucoTab@MobileCare system by the home care nurse. The suggested insulin dose will be injected only when the responsible home care nurse feels safe with the suggested dose. At any time, the suggested dose can be overruled by the nurse and/or an additional glucose measurement can be taken.

3.2. End of study

The planned study duration is three months (at least four to six weeks with GlucoTab@MobileCare). The study will end either after three months, or if a participant is transferred to a nursing home or if a participant is transferred to the hospital for more than two weeks or as decided by the investigator. At the end of the study information regarding diabetes therapy will be obtained for the family doctor. Participants will continue the basal insulin therapy unless a therapy change is indicated by the investigator or the family doctor.

3.3. Withdrawal criteria

The following withdrawal criteria will apply: significant violation of the protocol or non-compliance, refusal of the participant to continue study and/or observations, repetitive false suggestions which could lead to hypoglycaemia and decision by the investigator that a termination of the study is in the participant's best medical interest.

3.4. Questionnaires

User acceptance parameters, such as practicability of Gluco-Tab@MobileCare, will be obtained before study start and at study end by using a questionnaire for home care nurses who are working with the GlucoTab@MobileCare system during the study. All feedback will be collected by the manufacturer (JR) in a feedback list for qualitative user acceptance feedback. Participants and their relatives will be interviewed regarding satisfaction with the GlucoTab@MobileCare system at study end.

3.5. Sample size calculation

This is a proof-of-concept study without group comparison. Under consideration of the study aim, it was decided that a number of ten participants will be sufficient to be included into the study.

3.6. Primary endpoint

The percentage of tasks (BG measurements, insulin dose calculations, insulin injections) that were performed following GlucoTab@MobileCare suggestions in relation to the total number of suggested tasks.

3.7. Main secondary endpoints

3.7.1. User acceptance

- User satisfaction with the system regarding the user interface, the provided functionality, user workload and support of treatment workflow
- Participant/relative and nurse user acceptance/practicability parameters as assessed by questionnaires
- Physician adherence to insulin starting dose suggestion
- Nurse adherence to suggested basal insulin adjustment/titration dose, to suggested long-acting insulin injection dose, to suggested short-acting insulin injection dose, to suggested timing of adjustment/titration dose, to suggested BG measurement frequency
- Total number of BG measurements that were suggested by the system
- Total number and percentage of missed BG measurements per day
- Number of additionally performed BG measurements per day

3.7.2. Safety

- Number of BG values below individual glycaemic target range according to health status
- Number of BG measurements per day
- Differences between BG values entered in GlucoTab@MobileCare and BG values recorded by AccuChek® Guide
- Amount of injected insulin dose (total daily dose, basal insulin dose, bolus insulin dose)
- Number of performed and non-performed insulin injections per day
- Number of insulin injections suggested by the system per day
- Finding of basal insulin start dose (according to algorithm or as judged by investigator)
- Number of AEs, serious adverse events (SAE), device-related adverse events and serious device-related adverse events

3.7.3. Efficacy

- Number and percentage of FBGs in the FBG target range according to health status
- Mean pre-breakfast BG, mean pre-lunch BG, mean pre-dinner BG, mean daily pre-meal BG overall and per treatment day
- Number and percentage of BG values in the following ranges: 0–3.8 mmol/L, 3.9–10.0 mmol/L, > 10.0 mmol/L, 0–2.2 mmol/L, 0–2.9 mmol/L, 0–4.9 mmol/L, 3.9–7.2 mmol/L, 3.9–8.3 mmol/L, 5.6–10.0 mmol/L, 10.1–14.4 mmol/L, 14.5–19.4 mmol/L, ≥ 19.5 mmol/L
- Insulin starting dose
- Insulin end dose
- Number and percentage of FBGs < FBG target or > FBG target
- Days with FBGs in target according to health status

3.8. Planned statistical data analysis

All analyses will be conducted on an intention-to-treat basis. All participants who will be included in the study will be part of the database. Means/standard deviations or medians/interquartile ranges will be used to describe the outcome variables. Categorical variables will be presented as counts and percentages. All adverse events (AE) will be classified by severity and causality. Additionally, frequency tables of severity and causality will be presented. No subgroup analyses and no interim analyses will be performed. A detailed description of all statistical analyses will be presented in a Statistical Analysis Plan, which will be finalised prior to data analysis. Data analysis will be performed using SAS 9.4.

3.9. Safety analysis

Safety reporting will be conducted according to ISO 14155. AEs, SAEs, serious adverse device effects (SADEs) and suspected unexpected serious adverse events (SUSAR) will be recorded and if necessary reported according to local requirements for each participant in the respective form.

A summary of all potential known AEs/SAEs and risks of the medical device, the handling of potential foreseeable AEs/adverse device effects (ADE) and SAEs/SADEs etc. are listed in a standard operating procedure. The ethics committee of the MUG and the AGES will be informed about any SAEs and SUSARs that occur during the study.

Hypo- and hyperglycaemic episodes that can be treated at home will be recorded but will not be considered AEs. Severe hypoglycaemia will be recorded as AEs, hypo- and hyperglycaemic events that occur during study observation leading to the transfer to an emergency department will be recorded as SAEs.

3.10. Study monitoring

Monitoring will be conducted to ensure that the human subject protection, study procedures, study intervention administration, and data collection processes will be of the highest quality and meet the sponsor's (MUG), ICH E6 and regulatory guidelines.

A qualified monitor will verify adherence to protocol and local requirements, to perform source data verification and assist the investigator in study related activities.

3.11. Data management

Participant identification details will be anonymised by coding them to an identification number. This will be performed with strict adherence to professional standards of confidentiality, and the data will be filed under adequate security and restricted accessibility. Personal participant's details will be known only to investigators, home care nurses and researchers from MUG and JR who will be directly involved in the study. All persons who will receive access to participant's data underlie the Austrian Data Privacy Act in its current version and the General Data Protection Regulation.

Data will be recorded in the GlucoTab@MobileCare system, the participant's source data form and on electronic case report forms in the application OpenClinica®. The investigator will ensure the accuracy, completeness, legibility and timeliness of data reported in all required reports. Any change or correction will be dated, initialled and explained and must not obscure the original entry, this will apply to both written and electronic changes.

All data relating to the study will be stored securely in the investigator's archives as specified in section 8 of ICH GCP, and as required by the applicable regulatory requirement, for the legally required duration of archiving.

3.12. Indemnity

Insurance for any harm to life or health caused by the study will be provided for all study participants according to local legal requirements.

4. Discussion

In this proof-of-concept study the user acceptance, safety and efficacy of the basal and basal-plus insulin algorithm incorporated in the GlucoTab@MobileCare system will be investigated in participants with insulin treated type 2 diabetes receiving home health care.

The GlucoTab@MobileCare system has been modified for patients

receiving home health care and will be investigated for the first time in this setting. We expect improved quality and safety of basal insulin therapy in older adults by using standardised workflow protocols and insulin titration protocols. Thus, the uncommon de-intensification of diabetes medication in the elderly (26) will be counteracted and a reduction of hypoglycaemic events (24), leading to reduced acute hospitalisations will be strived for. Further, standardised support and empowerment for nurses with a simultaneous relief for physicians is expected.

Limitations are that this study does not fully reflect routine diabetes care, as the study physicians employed at the diabetes outpatient clinic were responsible for the medical treatment as opposed to their family doctors. We anticipate that the results of this study will help us design larger studies in routine diabetes care.

The study is registered at the German Clinical Trials Register (DRKS00015059). The study results will be published in a peer-reviewed journal and will be presented at conferences in the field of diabetes research and/or geriatric care.

Ethics approval

The study was approved by the ethics committee of the MUG, Austria (EK. No. 30–287 ex 17/18) and was registered and approved by regulatory authorities (AGES).

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Authors' contributions

Angela Libiseller: conzeptualization, methodology, project administration, writing - original draft.

Julia Kopanz: conzeptualization, methodology, visualization, writing - original draft.

Katharina M. Lichtenegger: funding acquisition, conzeptualization, methodology, writing – review & editing.

Julia K. Mader: conzeptualization, methodology, investigation, writing – review & editing.

Thomas Truskaller: software, data curation, writing – review & editing.

Bettina Lackner: data curation, formal analysis, validation, writing – review & editing.

Felix Aberer: investigation, writing – review & editing.

Marlene Pandis: investigation, writing – review & editing.

Johanna Reinisch-Gratzer: resources, writing – review & editing.

Gisela C. Ambrosch: project administration, writing – review & editing.

Frank Sinner: funding acquisition, writing – review & editing.

Thomas R. Pieber: funding acquisition, writing – review & editing, supervision.

Klaus Donsa: conzeptualization, methodology, software, project coordination, formal analysis, writing – review & editing, visualization.

Declaration of competing interest

JM, FS, TP and KD are founders of the decide Clinical Software Ltd.

JM is a member in the advisory board of Boehringer Ingelheim, Eli Lilly, Medtronic, Prediktor A/S, Roche Diabetes Care, Sanofi-Aventis and received speaker honoraria from Abbott Diabetes Care, Astra Zeneca, Dexcom, Eli Lilly, NovoNordisk A/S, Roche Diabetes Care, Servier and Takeda.

FA received speaker honoraria from Astra Zeneca, Boehringer Ingelheim, Eli Lilly and MSD.

TP is a member in the advisory board of Arecor, Novo Nordisk, Sanofi, Astra-Zeneca, Adocia and received speaker honoraria from Novo Nordisk.

The remaining authors have no relevant competing interests to disclose.

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