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DiaFocus: A Personal Health Technology for Adaptive Assessment in Long-Term Management of Type 2 Diabetes

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Type 2 diabetes (T2D) is a large disease burden worldwide and represents an increasing and complex challenge for all societies. For the individual, T2D is a complex, multi-dimensional, and long-term challenge to manage, and it is challenging to establish and maintain good communication between the patient and healthcare professionals. This paper presents DiaFocus, which is a mobile health (mHealth) sensing application for long-term ambulatory management of T2D. DiaFocus supports an *adaptive* collection of physiological, behavioral, and contextual data in combination with ecological assessments of psycho-social factors. This data is used for improving patient-clinician communication during consultations. DiaFocus is built using a generic data collection framework for mobile and wearable sensing and is highly extensible and customizable. We deployed DiaFocus in a 6-week feasibility study involving 12 patients with T2D. The patients found the DiaFocus approach and system useful and usable for diabetes management. Most patients would use such a system, if available as part of their treatment. Analysis of the collected data shows that mobile sensing is feasible for longitudinal ambulatory assessment of T2D, and helped identify the most appropriate target users being early diagnosed and technically literate T2D patients.

CCS Concepts: • **Human-centered computing** → **Ubiquitous and mobile computing**; • **Applied computing** → Health informatics.

Additional Key Words and Phrases: diabetes, mobile health, mHealth, mobile sensing,

*AJ was employed by Roche at the time of this research.

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1 INTRODUCTION

Diabetes mellitus is one of the major healthcare challenges society faces today, with the global incidence estimated to reach approximately 700 million by the year 2045 [60]. Type 2 diabetes (T2D) accounts for the vast majority of diabetes cases and is primarily characterized by peripheral insulin resistance and hyperglycemia. Although T2D typically manifests at an advanced age, in recent years the proportion of younger patients has been increasing continuously, causing reason for concern [37]. Indeed, this worrying trend is primarily routed in an increased prevalence of obesity, the widespread emergence of unhealthy dietary habits, and a generally more sedentary lifestyle. Over time, uncontrolled T2D can result in both microvascular (e.g. nephropathy, neuropathy) and macrovascular (e.g. atherosclerosis, coronary artery disease) complications that, in turn, have a negative effect on morbidity and mortality.

There are multiple therapeutic options available for the treatment of T2D, including lifestyle interventions (physical activity and diet), oral antidiabetic medications, basal insulin therapy, and intensified insulin therapy, depending on the severity of the disease [19]. Yet despite the widespread availability of these interventions, a substantial proportion of people living with diabetes around the world still do not reach their therapeutic targets in terms of blood glucose levels (as measured by Hemoglobin A1c (HbA1c)), blood pressure and cholesterol [64]. This has multiple underlying causes, including clinical inertia, insufficient therapy adherence, and a lack of sufficient patient empowerment, all of which contribute to sub-optimal diabetes care and warrants attention when developing and implementing disease management strategies [4, 5, 31, 34, 39, 41].

The integrated personalized diabetes management (iPDM) approach offers a structured disease management process that leverages structured documentation and fosters communication between patients and their treating healthcare professionals (HCPs) [17]. The iPDM concept, consisting of six steps that are repeated over the continuum of care, has been shown to significantly improve glycemic outcomes for people living with T2D on insulin therapy in the randomized, controlled PDM-ProValue study program [30, 43, 44]. The study program enrolled 907 patients from primary care or specialized diabetes practices and compared an iPDM intervention with usual care over 12 months. iPDM not only significantly improved HbA1c levels but also resulted in better adherence as well as higher treatment satisfaction as perceived by patients and their treating clinicians, supporting the notion of iPDM as a valid treatment option for improving clinical and patient-reported outcomes. However, the original iPDM approach did not provide a digital patient-centric tool to facilitate the patient to be closer involved in the structured process; the patient was merely asked to collect blood glucose data using a standard Blood Glucose Monitor (BGM) in-between visits to the clinic,while patient-reported outcomes were collected in paper form. The inclusion of additional digital patient-centric tools that augment the iPDM journey holds promise to further improve these outcomes for people living with T2D [36].

In this paper, we present the design, implementation, and technical feasibility study of DiaFocus, which is a novel smartphone-based system to collect behavioral and patient-reported healthcare information with the goal of improving the communication processes between patients and their treating clinicians. DiaFocus is designed to be the patient-centric tool that keeps patients engaged in the iPDM treatment process. Specifically, DiaFocus implements a multi-sensory approach that combines passive mobile sensing of the patient's behavior, physiological measures of blood glucose, experience sampling, and patient-reported healthcare information. DiaFocus implements an '*adaptive assessment*' approach, which implies that the collection of sensor data and experience sampling is adapted according to the specific diabetes focus area, which is agreed upon between the

patient and physician in order to improve and focus the patient-physician consultations. Moreover, in addition to the assessment of the behavioral and physiological aspects of the patient's health, DiaFocus has a distinct focus on the assessment of the *psycho-social* aspects of handling T2D over an extended period of time. This broad assessment and insight into the patient's life support the patient-clinician communication and help structure the treatment and care in the iPDM treatment approach.

DiaFocus was designed in a user-centered design process involving a wide range of end-users, including medical doctors, nurses, care and rehabilitation workers, and people with T2D. DiaFocus is implemented using a general-purpose software architecture for mobile sensing and mobile health, which allows for easy extension with, e.g., medical devices for glucose measures, other passive sensing modalities, or other patient-reported surveys. DiaFocus was subject to a 6-week single-arm technical feasibility study involving 12 patients, which gave valuable feedback on the technical stability, usability, and usefulness of the app and its use in T2D management.

2 BACKGROUND AND RELATED WORK

DiaFocus is designed as a personal health technology [10] enabling adaptive assessment of physiological, behavioral, and psycho-social parameters for patients with T2D. This section provides some background on T2D with a particular focus on the importance of assessing the psycho-social context of the patient and discusses other diabetes-related personal health technologies.

2.1 Type 2 Diabetes

T2D poses several challenges for the person living with diabetes and their supporting HCPs. Firstly, it is mainly asymptomatic until an individual starts to experience the onset of diabetes complications. None of the markers of diabetes management, elevated blood glucose, elevated blood pressure, or elevated cholesterol, in the range we typically see in people with T2D are associated with any symptoms. Thus as people engage in their everyday life, there is nothing that tells people how they are doing unless they actively monitor these things. With the recent introduction of continuous glucose monitors, it is easier to check how blood glucose is doing, but these devices are expensive and rarely used by T2D patients. Along with the minimal symptoms, there is also the challenge of the time lag and duration of effort that is required. Managing diabetes effectively takes years of persistent effort, with the only outcome being to avoid developing complications.

For the patient, the ongoing management of diabetes is a tremendous task. To manage T2D effectively and avoid its long-term complications usually means changing dietary choices, increasing activity levels, stopping smoking, reducing alcohol consumption, taking multiple medications every day, and some need to inject insulin treatments. All of this has to be done while constantly monitoring own health and trying to coordinate all these different components while keeping physiological parameters like blood glucose levels, blood pressure, weight, and cholesterol in the ranges that prevent complications.

For these reasons, it is well-known that people struggle to manage their diabetes. Despite the availability of technical innovation and new drug treatments, the outcome of diabetes care is not improving, with the majority of people still not getting to treatment targets [38]. The most recent large-scale longitudinal data on the success of diabetes care shows that diabetes care outcomes have deteriorated in the last few years [24].

These poor outcomes probably reflect the challenge of living and managing diabetes, with current estimates that many individuals are not taking their medications [40] accompanied by low levels of physical activity and less than optimal dietary choices. Given people understand the consequences of not managing their diabetes well, it is no surprise that depression rates are $1.5 - 2$ times higher in people with diabetes than in the general population [29] and with a third of people experiencing clinically significant levels of diabetes distress [54]. As a result, there is an increasing number of national and international guidelines and standards calling for the

provision of psycho-social care to be part of diabetes services and for the psycho-social well-being of individuals to be assessed as part of routine primary care of diabetes [22, 72].

2.2 Psycho-Social Assessment

While guidelines assert the need to provide psycho-social care to people with diabetes and provide guidance on what should be done, there is little clear guidance on how this should be done. The American Diabetes Association's general considerations for psychological care recommends [72] that:

(1) Psycho-social care should be integrated with collaborative, patient-centered medical care and provided to all people with diabetes, with the goals of optimizing health outcomes and health-related quality of life.
(2) Providers should consider an assessment of symptoms of diabetes distress, depression, anxiety, and disordered eating and cognitive capacities using patient-appropriate standardized / validated tools at the initial visit, at periodic intervals, and when there is a change in disease, treatment, or life circumstance. Including caregivers and family members in this assessment is recommended.
(3) Consider monitoring the patient's performance of self-management behaviors as well as psycho-social factors impacting the person's self-management.
(4) Consider assessment of life circumstances that can affect physical and psychological health outcomes and their incorporation into intervention strategies.
(5) Addressing psycho-social problems upon identification is recommended. Suppose an intervention cannot be initiated when the problem is identified during the visit. In that case, a follow-up visit or referral to a qualified behavioral health care provider may be scheduled during that visit.

In the context of an already stretched healthcare system, this is a lot of additional activity and care to provide to people with diabetes. In addition, there is an apparent skill set deficit in the current profile of healthcare professionals in the multidisciplinary healthcare team. For instance, Segal et al. [62] undertook a needs assessment of the skill mix needed to provide care to 1,000 people with diabetes. They established this would require 1.98 psychologists per 1,000 people with diabetes and 1.57 social workers. Research examining the availability of psycho-social care in pediatric and adult contexts clearly shows that current provisions fall well short of this [18, 33, 55]. This shortfall in available psychological services and professionals could be addressed by providing the current multidisciplinary diabetes care team (most commonly medic, nurse, and dietitian), with the necessary knowledge and skills to undertake assessments of individuals' psycho-social care needs and provide or refer to appropriate support or treatment services. At least one survey of people with diabetes indicates this would be their preferred model of psychosocial care provision [32]. Unfortunately, there are few programs providing training for HCPs on how to provide psychological care and assessment for people with diabetes.

Given the shortage of psychologists, and the absence of a psychologically skilled diabetes care workforce, there is clear scope for using digital technologies to facilitate the assessment of psychological issues, which can then be used to inform clinical discussions with HCPs. There have been several tools developed and preliminary work undertaken showing that such computerized assessment of psycho-social aspects of diabetes are well received by people with diabetes and can enhance the interactions between people with diabetes and their health care team and can serve to lead to improvements in care outcomes [12, 20, 26, 50, 59, 63, 69]. However, even with this bulk of evidence base, it is uncommon to see specialist diabetes services routinely utilizing these assessment tools. This may be due to the extended duration of the assessment, the need for training HCPs on what to do with the results, the inability to integrate data from assessments into medical records, or the lack of time or money to implement such assessment programs. However, it is important to note that these studies have almost exclusively undertaken in specialist diabetes centers, yet the bulk of diabetes care takes place in the primary care context. Thus there is a clear need to support primary HCPs to assess and identify people's psychological needs and provide appropriate responses to these. This requires further refinement of our current lengthy assessment

tools, which are targeted, tailored, and adaptive to optimize the engagement of the person with diabetes and their HCPs.

2.3 T2D mHealth Systems

Numerous mHealth solutions have been designed, built, and studied for self-management of T2D, mainly focusing on tracking physical activity, behavior, and diet, and providing some basic education [1, 3, 16, 66–68, 70, 71, 74]. When asking patients about their perception of critical features for T2D mHealth solutions, they emphasized the benefits of self-monitoring changes in blood glucose, diet, and exercise [57]. A systematic review of reviews evaluating technology-enabled diabetes self-management technology found four key features as essential for improved HbA1c: (i) communication, (ii) collection of patient-generated health data, (iii) education, and (iv) feedback [27]. Most studies described metabolic monitoring and tracking of healthy eating and activity as the predominant self-care features. Most of these systems, however, have a static configuration of the parameters to monitor and do not allow for any adaptations to the needs of the patient or HCP.

As evident from these reviews, most mHealth tools for T2D focus on the assessment of physiological (e.g., blood glucose) and behavioral (e.g., physical activity or diet) data but much less often on mental health [2, 35], social, or well-being factors in general. However, research suggests the prevalence of depression as a comorbidity to diabetes is growing and that depression negatively affects glycemic control [61]. One approach to addressing mental health in diabetes is presented by Aguilera et al. [2], where the focus is on treating depression and diabetes through physical activity. The app uses goal setting and progress tracking through visualizations with active elements consisting of automated feedback messages based on a reinforced learning algorithm.

2.4 Contributions of DiaFocus

The main focus and contribution of DiaFocus is that it provides the conceptual, technological, user experience (UX) design of an mHealth system for the adaptive assessment and ambulatory management of T2D in primary care.

From a technical point-of-view, DiaFocus uses a data-driven mobile sensing architecture that can be used for – and extended to – collecting a wide range of both patient-reported and automatically collected data from mobile and wearable sensors. As such, the architecture of DiaFocus is extensible and allows for adding and configuring a broad repertoire of measures to be used in the adaptive assessment.

From a clinical viewpoint, DiaFocus is designed to support the iPDM treatment model. In comparison to other T2D mHealth technologies, DiaFocus takes an assessment of the patient's *psycho-social state* as the outset for further *adaptive assessment* of relevant physiological, behavioral, contextual, and self-reported data. DiaFocus is designed to be both a tool for self-tracking and reflection, as well as a dialogue tool between the HCP and the patient to be used during the iPDM treatment cycle. In contrast to other systems in this space, DiaFocus can be *personalized* to the individual patient by focusing on specific areas of concern.

3 RESEARCH METHODS

As illustrated in Figure 1, the design of the DiaFocus system was done in three main phases. In the first phase, a detailed analysis of the problem domain involving all stakeholders led to a set of requirements and system design ideas. This phase is described in section 3.2. Based on the detailed requirement specification and design done in phase one, the second phase focused on the technical design and implementation of the DiaFocus system. Several iterations with clinicians and patients were done during the second phase as the system evolved. The results from this second phase are described further in Section 5. Finally, the third phase involved a technical feasibility study aiming at investigating the technical stability, usability, and usefulness of the DiaFocus system. This is described in Section 6.

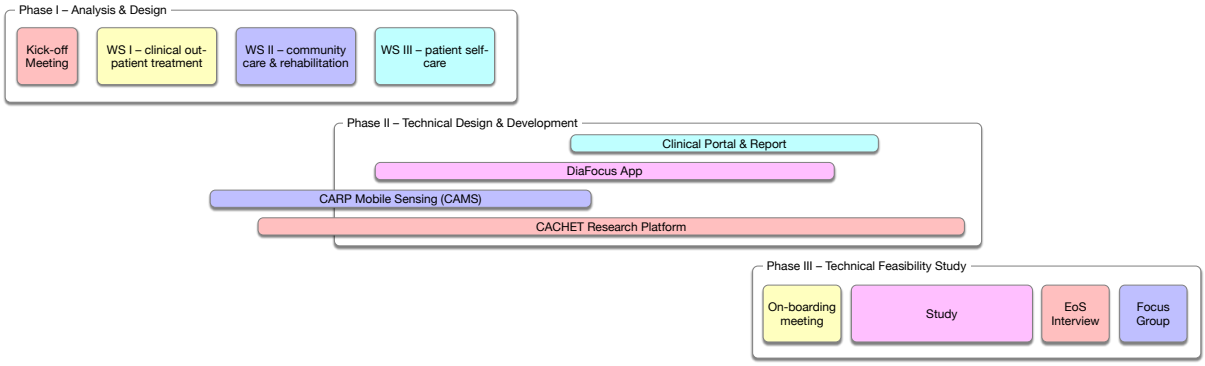


Fig. 1. Timeline of the analysis, design, implementation, and evaluation of the DiaFocus system.

The entire design, development, and evaluation process involved clinicians from Steno Diabetes Center Copenhagen (SDCC), which is a research hospital and health promotion center for the treatment of all types of diabetes, and Copenhagen Center for Diabetes (CCFD), which is a local community center for care and rehabilitation of T2D patients. Patients were recruited from these two centers. In total, the design activities spanned 12 months (April 2019 to March 2020) and involved 30 participants; 9 patients, 14 clinicians (endocrinologists (MDs), nurses, dietitians, and physiotherapists), and seven designers, computer scientists, and engineers.

3.1 Analysis and Design

The design of the DiaFocus system followed a participatory user-centered design (UCD) approach [28, 49], applying the Patient-Clinician-Designer framework (PCD) framework [48]. This research method seeks to find a suitable design compromise by considering different, and sometimes conflicting, concerns from the perspective of three stakeholder groups; the patient, the clinician, and the designer. The PCD framework provides a structured process for mediating co-design activities to find appropriate design solutions. The analysis and design process was organized around three separate co-creation ideation and design workshops, which involved medical doctors (endocrinologists), diabetes nurses, dietitians, and nutritionists from SDCC and CCFD, as well as a heterogeneous group of T2D patients (Figure 2). The main goal of the workshops was to (i) determine problems with the current approach and how DiaFocus can be tailored to suit patients' needs while also strengthening the communication between the patient and their doctor, and (ii) engage in rapid prototyping of the UX design of DiaFocus patient app.

The first workshop was held at SDCC, focusing on the clinical part of the system and aimed at establishing the overall requirements of the system in terms of clinical support for treatment and care of T2D. This workshop involved eight clinicians, including three nurses and five medical doctors from SDCC and CCFD, who had extensive experience with the treatment, care, and rehabilitation of T2D patients. The second workshop was held at CCFD and focused on the daily self-care by patients and how they could use the technology for better self-management of their chronic condition. The workshop included two nurses, two medical doctors, a dietitian, a nutritionist from CCFD and a nurse from SDCC. The third workshop was also held at CCFD and focused on the needs and ideas of T2D patients and the evaluation of an early interactive prototype of the DiaFocus patient app. The workshop included nine patients (2/7 female/male) and a sub-group of clinicians who had also participated in the previous workshops. During this workshop, patients were able to talk about how they handled their T2D both in plenum and in pairs, provide ideas for the design of a smartphone app, and were able to use and explore an early prototype of the system.

Fig. 2. The three design workshops for DiaFocus: Workshop I focusing on the clinical setting and requirements for the clinical interface; Workshop II focusing requirements for care and rehabilitation; and Workshop III focusing on the patient's needs and the UX design of the app.

In all three workshops, participants engaged in a wide range of design activities, including identifying self-care barriers and priorities for T2D patients and their treatment, discussion of problems and opportunities using digital technology, designing specific future scenarios of treatment, self-care, and rehabilitation of T2D, role-playing new scenarios, and designing user interfaces like a dashboard for the clinicians and a smartphone app interface for the patient to be used in treatment, care, and rehabilitation. As shown in Figure 2, the workshops all resulted in a wide range of design artifacts– from paper-based sketches to interactive phone app prototypes – which formed the basis for documenting and specifying the design requirements for the system.

3.2 Requirement Specifications and System Design

The clinical and end-user requirements for the DiaFocus system were derived from the design workshops and were documented in a Requirement Analysis Document (RAD) following an object-oriented software engineering method [14]. The core functional requirements and design drawn from this process are described in section 4. In addition, several non-functional software architecture requirements related to security, hosting, data management, data protection (GDPR), etc. were identified and incorporated into the entire DiaFocus system design. Based on these requirements, available commercial systems and apps for diabetes self-management were reviewed, including the MySugr app [21] from Roche. However, none of these systems met the needs and requirements obtained from patients and HCPs and were not fit to support the iPDM process. Most of these systems are primarily designed for type 1 diabetes (T1D) patients and none of them support the adaptive assessment based on the patient's changing needs. Moreover, none of these systems incorporated the support for psycho-social assessment as part of diabetes management, which is core to the iPDM approach.

Therefore, a system and UX design of DiaFocus was initiated based on the obtained requirements. Following a user-centered design process, these requirements were gradually turned into a set of scenarios, use cases, domain models, and UX design mock-ups and prototypes of the DiaFocus patient app and clinical web interface. The design was subject to several iterations involving all the types of end-users mentioned above (patients, doctors, nurses, and social care workers). As shown in Figure 1 and 2, the last workshop started this iterative design process. Section 5 describes the final design of the DiaFocus system.

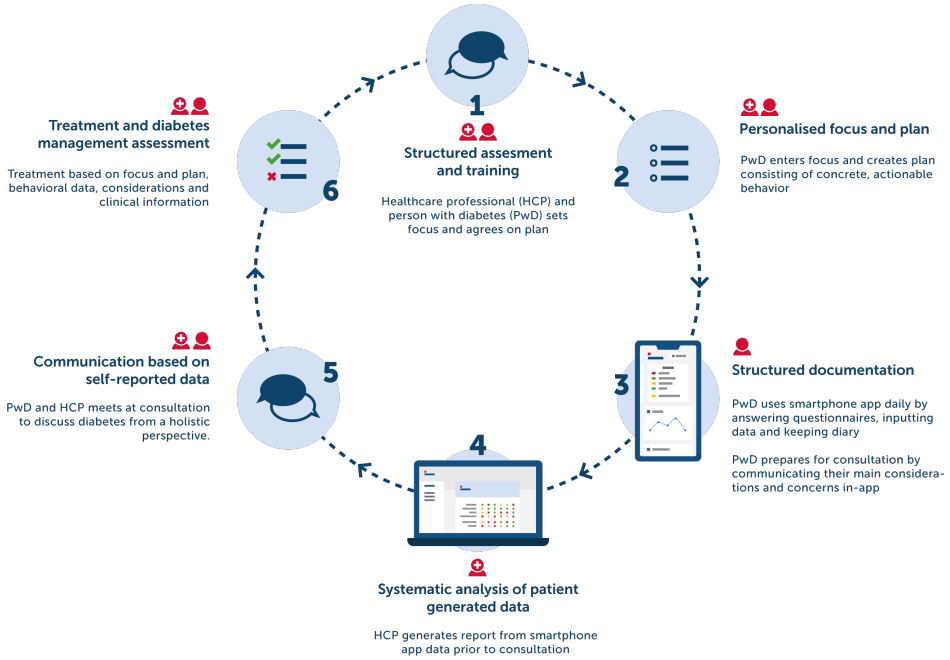


Fig. 3. The DiaFocus iPDM six-step cycle (adapted from [17]).

4 PSYCHO-SOCIAL ADAPTIVE ASSESSMENT IN DIABETES

The overall aim of the DiaFocus system is to support an adaptive assessment of the status of diabetes for a patient as part of the iPDM approach [17], as illustrated in Figure 3. DiaFocus focuses on supporting the dialogue between the patient and the HCP during regular consultations, including aspects of self-management capabilities and barriers. This is supported by collecting health status, psycho-social factors, and daily health and behavioral patterns from people diagnosed with T2D. The iPDM approach builds on strong clinical evidence that structured self-monitoring of diabetes (incl. blood glucose) has a positive impact on the treatment of T2D [23, 56] and leads to more frequent and effective physician interventions [58]. From a behavior change perspective, self-monitoring is the most widely employed strategy in interventions aimed at promoting health and wellness in mHealth applications [53]. The strengths of self-monitoring have shown to be its ability to early reveal problem behaviors, provide real and concrete information, foster reflection, make people accept responsibility, create awareness and raise users' consciousness about their health and wellness [52].

The system captures practical, reliable, and valid information about the patient's health, behavior, and psychological state as seen from the patient's point of view. The goal is to (1) identify the best treatment approach for each individual patient with T2D and (2) support and enhance the dialogue between the patient and the HCP, specifically General Practitioners (GPs), nurses, and rehabilitation and care providers. The overall goal is to improve clinician-patient communication and thereby improve clinical and patient-reported outcomes. To support this, the iPDM cycle consists of the following six phases (c.f., Figure 3):

(1) The cycle starts with a structured assessment and training during a meeting between the patient and the HCP in the clinic. This includes talking about focus areas and agreement on plans. At the first meeting, this also includes installing the DiaFocus app on the patient's phone, filling in the informed consent, and providing instruction on how to use it.
(2) At the first consultation a shared agreement between the HCP and the patient is made, which lists specific and individual goals for the coming period. A plan is created that has one or more focus areas such as 'smoking', or 'managing blood glucose'. A set of goals are entered into the system by the patient. Goals are concrete and actionable, like 'go for a walk every evening after dinner', or 'measure blood glucose levels every morning and evening'.
(3) In between consultations (3-4 months period), the patient engages with the DiaFocus smartphone app to collect health and behavioral data, fills in questionnaires, makes entries in the diary, and rates their progress on their focus areas. In parallel, the app automatically collects behavioral and contextual data (as described in Section 5 and Table 1).
(4) Prior to a consultation, the HCP can generate a report that summarizes and interprets the data collected by the patient. The report is annotated to alert the HCP of measures, responses, and other data to be aware of.
(5) During the consultation, the HCP and patient engage in a conversation based on the psycho-social, health, and lifestyle assessments presented in the report. Notes made by the patient in the diary are not shown in the report, but the patient can refer to these on the phone if relevant.
(6) The HCP uses the report to supplement their usual clinical assessment and decision-making. The consultation is concluded with a shared agreement on a new (or repeated) plan, including focus area(s) and goals.

Given this flow, the collection of patient-reported data is key to the clinical assessment of the patient. This includes an assessment of the physiological diabetes-related state, lifestyle information, and an assessment of psycho-social state and well-being. This is done by triggering a set of relevant questionnaires. Figure 4 shows the questionnaires used and the flow between them. Overall, there are three types of questionnaires: 'Patient information' (A), 'Diabetes health' (B), 'Areas of concern' (C), and 'Supplementary assessment' (D). Questionnaires A and B1 are collected once when the patient signs up. Questionnaires B2–B5 and C are collected on a regular basis (e.g., weekly, bi-weekly, or monthly) and before the consultation with the HCP. Questionnaires D1–D4 collects supplementary information and these questionnaires are only issued if answers in sections B or C identify certain areas to investigate further (e.g. sleep or food behavior).

The questionnaires were partly chosen from existing standardized and validated questionnaires and partly designed and adapted for the iPDM process and DiaFocus system by the involved researchers. Lifestyle information (B1) is collected using the Accu-Chek Interview Questionnaire [69] to asses psycho-social status and self-care motivation. The questionnaire was slightly optimized and adapted to the iPDM approach (see Appendix B.1 for the DiaFocus version). Emotional distress (B2) is collected using a questionnaire designed specifically for DiaFocus (see Appendix B.2). By using four publicly available datasets, we validated the predictive value of the B2 distress scales, to identify individuals that were distressed or depressed at a clinically significant level. The analysis showed good performance of the B2 form compared to other questionnaires. The B2 questionnaire exists in both a 2 or 6 questions form and both forms are used in DiaFocus. General well-being (B3) is captured using the WHO Well-being Index (WHO-5) [13]. The diet and exercise (B4) and blood glucose (B5) surveys comprise a relevant subset of questions from Accu-Chek Interview Questionnaire (B1). The list of areas of concern (C) is compiled based on input from all HCPs and patients involved in the design process (see Appendix B.3 for the list). Food behavior (D1) is collected using a questionnaire developed specifically to DiaFocus by the clinicians and dietitians from SDCC and CCFD (see Appendix B.4). D2, D3, and D4 are collected using standardized questionnaires recommended by clinical researchers. Sleep quality and patterns (D2) are collected using the Pittsburgh Sleep

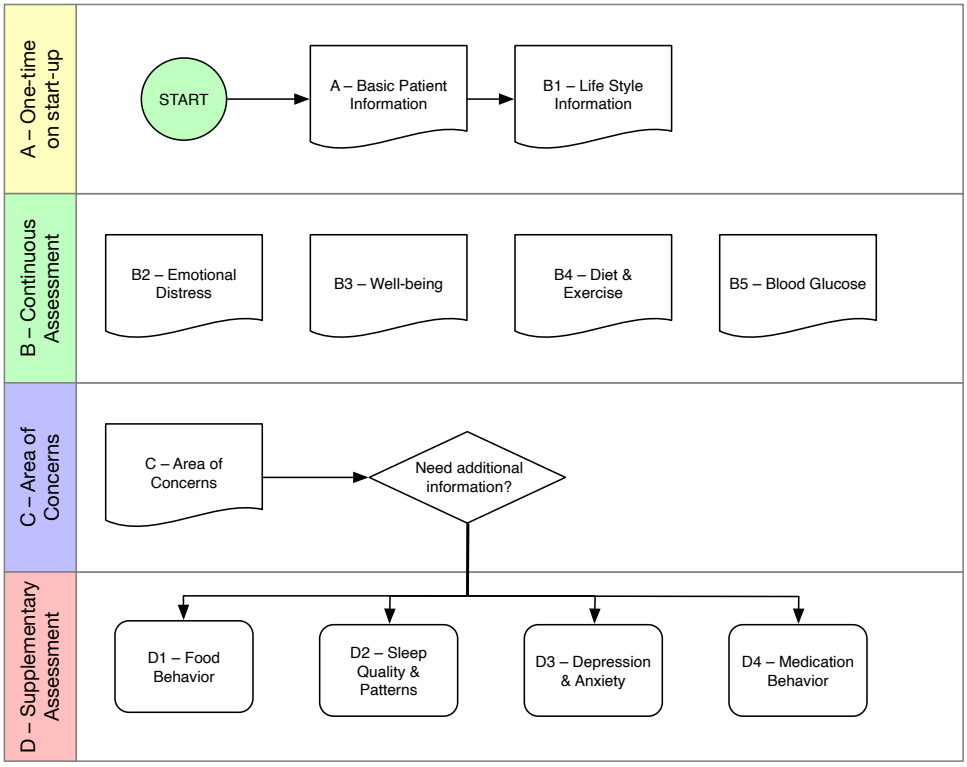


Fig. 4. The flow of questionnaires in DiaFocus starts from when the user installs the app, signs in, and starts using the application. The questionnaires and their timing are listed in Table 1.

Quality Index (PSQI) questionnaire [15]; depression and anxiety (D3) are captured using the Hospital Anxiety and Depression Scale (HADS) [73]; and medication-taking behavior (D4) is assessed using the Danish Medication Adherence (MA) [25] scale (see Appendix B.5 for an English translation of MA).

To support structured documentation and data collection (step 3 in Figure 3), the DiaFocus system implements an *adaptive assessment approach*, which continuously adapts what data is collected from the patient and later used in the dialogue with the HCP. This adaptive assessment approach consists of three main parts:

(1) Together the patient and HCP can *personalize* data collection between consultations by setting up a so-called 'chapter' which contains a list of focus areas for the patient to attend to for the next consultation. As illustrated in fig. 8a focus areas could be to 'quit smoking' or 'improve blood glucose monitoring'.
(2) Depending on the focus area(s) selected, DiaFocus automatically *configures* itself to start capturing relevant data. This could be patient-reported data like the number of cigarettes smoked, automatic collection of blood glucose from the patient's BGM device, or collection of step counts from the phone.
(3) The questionnaires issued to the user is automatically adapted based both on the selected focus areas as well as the answers provided by the patient. For example, if the patient has a focus area of 'Food, eating and alcohol habits', DiaFocus will issue the 'Diet & Exercise' questionnaire. Similarly, if the patient reports depressive symptoms in the 'Emotional Distress' questionnaire (B2), then DiaFocus will issue the 'Depression & Anxiety' questionnaire (D3).

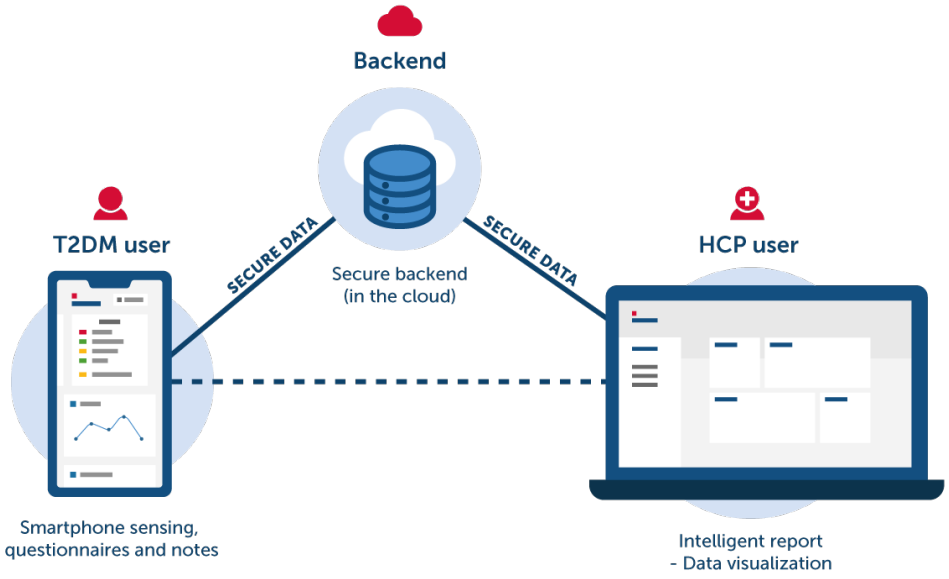


Fig. 5. The overall architecture of the DiaFocus system comprising of the Copenhagen Research Platform (CARP) cloud-based back-end, the DiaFocus smartphone app, and the clinical web application with associated reports.

5 SYSTEM DESIGN

Figure 5 shows the overall system architecture of the DiaFocus system. It is a client-server architecture comprising of a cloud-based infrastructure and two client applications; the patient smartphone app and the clinical web application. The architecture is implemented using a set of open-source software components and libraries maintained as part of the Copenhagen Research Platform (CARP)[1].

5.1 DiaFocus Smartphone Architecture

Figure 6 shows the overall software architecture of the DiaFocus mobile app, which runs on the patient's smartphone collecting passive and patient-reported data. The DiaFocus app consists of a set of dedicated UI screens (marked red in Figure 6), which implement the UI design shown in Figure 7 and 8. DiaFocus is implemented using two open source frameworks; the CARP Mobile Sensing (CAMS) framework [7][2] and the Research Package framework[3], which in turn consist of a number of sub-components (all marked green and purple in Figure 6). CAMS is a cross-platform (iOS and Android) extensible framework for implementing mobile sensing apps and comes with a long list of options for data collection, data management, data anonymization, battery optimization, and data upload [9]. All data collection and management in DiaFocus is handled by CAMS. Research Package handles the informed consent flow (including collecting a signature from the patient), as well as all the psycho-social surveys used for patient-reported data collection. By leveraging CAMS and Research Package only the application-specific functionality is implemented in DiaFocus.

[1]Copenhagen Research Platform (CARP): http://carp.cachet.dk/ (Accessed November 2022)
[2]CARP Mobile Sensing (CAMS): https://pub.dev/packages/carp_mobile_sensing/ (Accessed November 2022)
[3]Research Package: https://pub.dev/packages/research_package/ (Accessed November 2022)

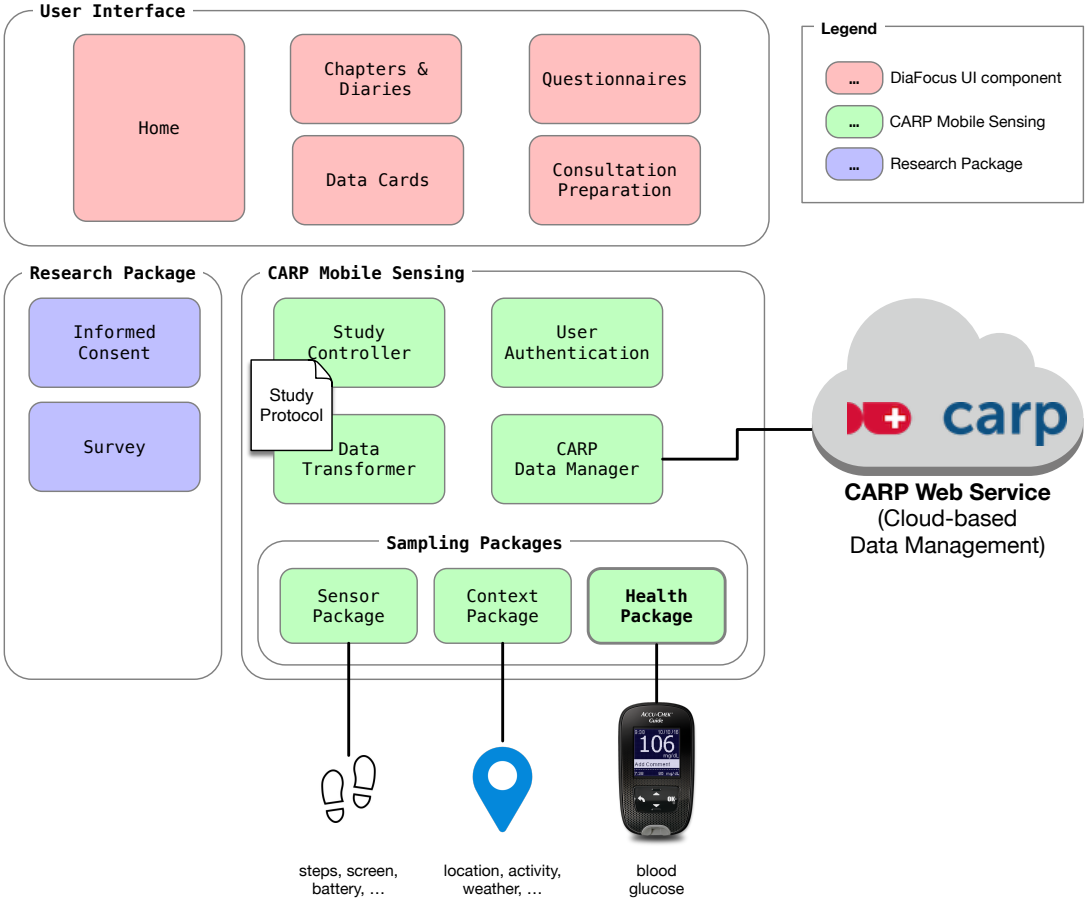
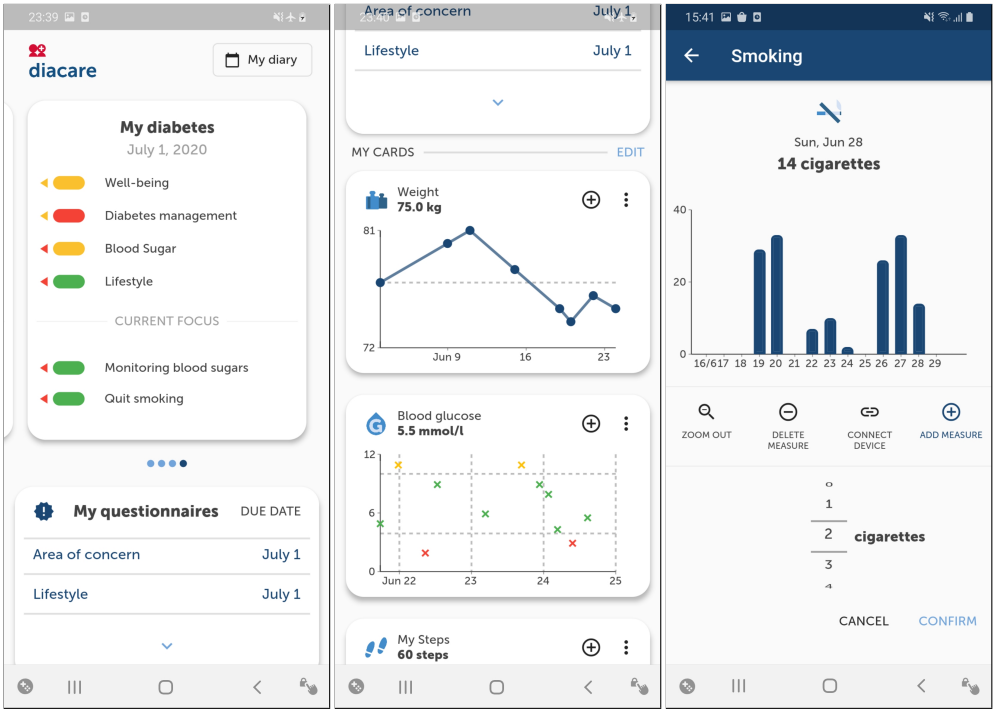


Fig. 6. Architecture diagram of DiaFocus app (red components) and its use of the CARP Mobile Sensing (CAMS) (green components) and Research Package (RP) frameworks (purple components), and integration to the Accu-Chek BGM using the 'Health' sampling package. The red user interface (UI) components of DiaFocus is shown in Figure 7 and 8.

Data sampling is configured as a 'Study Protocol' in CAMS and the execution of data collection is handled by a 'Study Controller', which is responsible for collecting and transforming the data according to the protocol specification. In DiaFocus, the data is uploaded to and stored in the CARP Web Service, which is a cloud-based infrastructure for managing and analyzing mHealth data.

A set of sampling packages can be 'plugged into' CAMS and they are responsible for handling data sampling. For example, contextual data like location and activity (see Table 1) is collected by the `ContextPackage`. Similarly, step counts from the pedometer sensor in the smartphone are collected via the `SensorPackage`. Each sampling package encapsulated access to the operating system (OS) sensors and typically uses one or more plugins to access the OS level sensors.

Integration between DiaFocus and the Accu-Chek Guide BGM is done using Apple Health. By using the Accu-Check Connect app on iOS, data from the Accu-Check Guide BGM can be synchronized with the Apple



(a) (b) (c)

Fig. 7. The UI design of the 'Home' and 'Data Card' pages of the DiaFocus mobile app (final design). (a) Home page showing the diabetes status overview and the list of surveys to answer. (b) Home page showing the list of 'Data Cards' each showing collected data, both from sensors and patient-reported. (c) Patient-reported data entry of a 'measure' (number of smoked cigarettes).

Health database on the phone. By using the `HealthPackage`[4], CAMS and thereby DiaFocus can collect this BGM data. In order to support cross-platform sensing, the Health Package can also collect data from Google Fit. However, since the Accu-Chek Connect app for Android does not support Google Fit, DiaFocus only collects blood glucose data directly from BGM devices on iOS. Therefore, on Android, the user has to self-report blood glucose data in the app.

5.2 DiaFocus Smartphone User Experience

As shown in Figure 6, the DiaFocus app has UI components for (i) user authentication to CARP, (ii) filling in the informed consent, (iii) a home page, (iv) filling in questionnaires, (v) handling chapters and diaries, (vi) showing data cards, and (vii) consultation preparation. User authorization to CARP is handled by CAMS and the informed consent flow and the questionnaires are implemented using RP and use the UI components provided by these packages.

Figure 7a shows the home page of the app. The top card (rounded box) represents the current chapter and shows how the patient is doing in terms of handling his/her diabetes along four core parameters: well-being, diabetes management, blood sugar, and lifestyle. Each field is color coded (green/yellow/red) reflecting how

[4]CARP Health Package: https://pub.dev/packages/carp_health_package/ (Accessed November 2022)

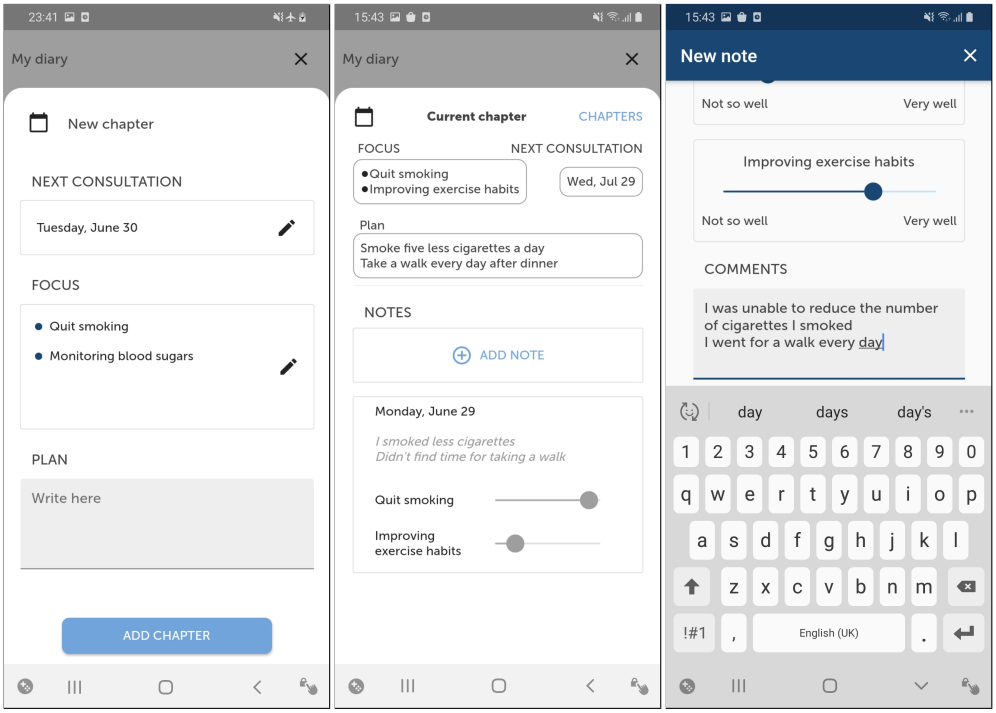


Fig. 8. The UI design of the 'Chapter' pages of the DiaFocus mobile app (final design). (a) Creating a new Chapter with time for the next consultation, the focus areas, and the plan. (b) Review of the current chapter rating how each focus area is doing. (c) Entering a note for a focus area.

the patient is doing. These four parameters are always visible as these were decided to always be relevant for patients with T2D. The parameters listed under 'Current focus' reflect the focus areas selected for this chapter. The color coding is based on data reported by the user in the different surveys (B, C, and D). Previous chapters can be accessed by scrolling left and the left-hand-side arrows indicate how the user was doing in the previous chapter period. Beneath, in the "My questionnaires" box the user can see and access any active questionnaires that require a response.

Figure 7b shows how each health- and lifestyle measure (e.g., weight, smoking, steps) have a card that shows a historical overview of the data collected. Data cards serve the dual function to display how the user is doing and to make manual inputs and measurements, as shown in Figure 7c. Cards are automatically shown or hidden depending on chosen focus area(s) but can also manually be toggled on/off by the user. Cards show both patient-reported data (like alcohol intake or smoking) as well as data collected automatically (like step count or blood glucose measures from the BGM device).

To support the dialogues between the patient and the HCP, DiaFocus supports the features of setting 'Focus Areas' and maintaining a 'Diary' with a set of 'Chapters'. During the consultation (step 2 in the iPDM cycle in Figure 3), the patient and HCP collaborate on creating a new chapter for the period until the next consultation (Figure 8a). This entails entering the date of the next consultation, choosing 1–3 focus areas (like 'Reduce smoking' or 'Start measuring blood glucose'), and specifying concrete goals for each area (like 'Smoke maximum 3 cigarettes

Parameters	Type	Source	Sampling rate
Battery	S	Phone	EB
Screen	S	Phone	EB
Noise	S	Phone	once pr minute
Location	S	Phone	EB
Activity	S	Phone	EB
Weather	S	Phone	hourly
Steps	S	Phone	EB
Blood glucose	S/PR	BGM/Patient	daily
Smoking	PR	Patient	daily
Weight	PR	Patient	daily
Alcohol	PR	Patient	daily
B1 Lifestyle	PR	Patient	once
B2 Emotional distress	PR	Patient	bi-weekly
B3 Well-being	PR	Patient	bi-weekly
B4 Diet & exercise	PR	Patient	weekly
B5 Blood glucose	PR	Patient	monthly
C1 Area of Concern	PR	Patient	monthly
D1 Food behavior	PR	Patient	conditional
D2 Sleep quality and patterns	PR	Patient	conditional
D3 Depression and anxiety	PR	Patient	conditional
D4 Medication behavior	PR	Patient	conditional

Table 1. Data features collected in DiaFocus with source and sampling rate. S: Sensed. PR: Patient-reported. EB: Event-based. BGM: Blood Glucose Monitor. The top part shows mobile sensing parameters, the middle part diabetes-related physiological and behavioral parameters, and the bottom part the patient-reported parameters as collected via surveys.

per day' or 'Measure blood glucose every morning before breakfast'). Creating a new chapter closes any previous active chapter for editing, but the previous chapters can still be reviewed. While using the app at home (step 3 in the iPDM cycle in Figure 3), the diary allows the patient to rate how they are doing within each of the active focus areas s/he has selected (Figure 8b), and make entries with personal notes (Figure 8c). The diary reflects the active chapter and shows the focus areas and goals set during the consultation. The user can make entries as free text, and rate how they are doing with their individual focus area(s). Prior to the next consultation (step 5 in the iPDM cycle in Figure 3), the user is asked to enter their considerations (areas of concern) reflecting what they would like the next consultation to be about. The user can choose from predefined considerations or input their own. The user rates how important and how confident they are with each consideration.

5.3 DiaFocus Smartphone Data Collection

DiaFocus is designed to collect a wide range of data types. Table 1 shows an overview of the data being collected, which includes both automatically sensed data like step count and activity, patient-reported data like smoking and weight, and questionnaire data like the WHO-5 and MA questionnaires. See Appendix B for the details on the questions in each survey.

Due to the plugin architecture of CAMS [9], other devices collecting blood glucose or other kinds of data can be used in DiaFocus. For example, by plugging in a sampling package that collects weight data from a connected

scale (e.g., Withings), the DiaFocus app could be collecting and displaying such data also, without changing anything in the app itself. Similarly, the list of surveys can be extended dynamically and issued to the user. Hence, the software architecture of DiaFocus is designed to be highly extensible and able to accommodate the collection of new types of data from devices, mobile sensing, and patient-reported questionnaires.

5.4 Clinical Web Application and Report

The HCP can prepare for the consultation (step 4 in the iPDM cycle in Figure 3) by downloading a report from the clinical web application. See Appendix D for an example of such a clinical report. The report provides a full summary of the data collected since the last consultation with the patient. This includes: (i) a summary section showing the current colored fields of the focus areas, (ii) a historical overview of all previous chapters (consultations), (iii) the list of considerations reported by the patient to be in focus for the upcoming consultation, and (iii) a series of graphs and tables summarizing the measures collected and the responses to the questionnaires. Any critical or important values or responses are highlighted in the report using colors or warning icons. All data from the app is visible in the report except for the patient's diary notes, which are kept only visible to the patient in the app. During the consultation (steps 5 and 6 in the iPDM cycle in Figure 3), the patient and HCP can share data and reflect on the progress since the last consultation, and start to make a new plan and chapter for the coming period.

6 TECHNICAL FEASIBILITY STUDY

Adhering to best practice in health technology design research, a single-arm feasibility study of DiaFocus was carried out to obtain a comprehensive understanding of its technical stability and performance, acceptability, usefulness, usability under free-living conditions [8, 42]. Klasnja et al. [42] recommend that in the early phase of design and evaluation of novel health technologies *"a deep understanding of the how and why of the system use by its target users should be a central goal for evaluations of systems"*. It is important to assess the technical and usability qualities of the system *before* moving into a clinical trial. Otherwise, technical and usability problems can strongly affect the clinical outcome. Specifically, understanding the reasons behind users' *acceptance* of technology is particularly important in the context of digital health interventions [51].

Specifically, the following aspects of DiaFocus system were investigated:

- Technical robustness including the collection of sensor-generated and patient-reported data.
- Acceptance, including perceived usefulness and usability in longitudinal use.

Hence, the purpose of the study was to investigate if the patient would be able and willing to use the DiaFocus assessment tool as part of the overall iPDM cycle (c.f., Figure 3) and the focus was on step 1, 2, and 3 in the cycle, and not on the clinical steps (i.e., step 4, 5 and 6). Therefore, no dedicated HCP were directly involved in the study. Participants were told that they were welcome to share the data with their regular GP and could share the report with them if they wanted. The use of DiaFocus in clinical treatment was to be the focus of a subsequent clinical trial. Due to its technical and non-clinical study objective, this technical feasibility study was exempted from ethical approval by the Danish Ethical Committee (Journal-no. H-20022169).

6.1 Methods

The study had five parts. First, at a two-hour start-up meeting the participant meet a researcher, was given time to review and sign both a digital and paper-based informed consent form, and had training in using the DiaFocus app and BGM. Detailed instructions on how to use the system during the study were given both orally and in a written instruction sheet. During the startup meeting, the participant was asked to create his or her first chapter by stating focus area(s) and plans (steps 1 and 2 in the iPDM cycle). Second, the participant used the DiaFocus app for up to ten weeks (70 days), during which s/he self-reported data and filled in the questionnaires, as they

were prompted (step 3 in the iPDM cycle). After four weeks of use (28 days), the participant was prompted by a researcher over the phone[5] to create a second chapter in the app. This was to initiate a second cycle. The participants were informed that the focus of the study was to evaluate DiaFocus and its use in self-monitoring of diabetes. They were also told, that no HCP would be part of the study or would review the data. However, the participant was encouraged to use the app and the focus areas noted down in the chapters during consultations with his or her regular doctor. Third, at the end of the study period (week 8), participants were asked to fill in the CACHET Unified Methodology for Assessment of Clinical Feasibility (CUMACF) questionnaire [6], which combines the Post Study System Usability Questionnaire (PSSUQ) [46] and the Unified Theory of Acceptance and Use of Technology (UTAUT) [65] questionnaires. This questionnaire is designed to assess the technology acceptance of DiaFocus. The questionnaire was issued online and the questions included are listed in Appendix A. Fourth, in order to obtain a more in-depth qualitative understanding of the participants' experience from using DiaFocus, 30–45 minutes post-study semi-structured one-to-one interviews with each participant were done over the phone. Fifth, a two-hour focus-group interview with 10 participants was held at SDCC. These interviews focused on elaborating topics in the questionnaire and collecting qualitative insights on the system, covering topics such as user experience, how it helped their diabetes management, and how they expected the system could support their disease and daily life, and covered participants' existing use of diabetes- and health-related technologies.

6.2 Technical Setup

Participants were asked to use their own smartphones for the study. DiaFocus was available for beta testing in the Google Play Store and in Apple TestFlight. During the start-up meeting, each participant was helped to upgrade their phone (if needed) and to download and install the app. If they were already using a BGM for measuring blood sugar levels, they were instructed to keep using this and enter the data in DiaFocus. Others were offered to borrow an Accu-Chek Guide BGM to be used for daily blood glucose measurements. The direct integration between the BGM and DiaFocus was not enabled; partly in order to have an equivalent technical setup between iOS and Android users (the integration only works on iOS via Apple Health), and partly because integration between the Accu-Chek BGM and Apple Health requires a 3rd party app (Accu-Chek Connect or MySugr), which we could not require the participants to install and use. Hence, participants using a BGM were asked to manually enter their BGM measures in DiaFocus.

6.3 Recruitment

Participants were recruited from SDCC and CCFD during September and October 2020. Inclusion criteria were: (i) 18 years or older, (ii) diagnosed with T2D, (iii) able to read and write Danish and/or English, (iv) own a smartphone, either a) an iPhone running iOS 13 or newer, or b) a smartphone running Android version 8.0 Oreo or newer. No restrictions were imposed on the participants regarding their use of their smartphones, so our analysis is conducted under usual and realistic conditions. Likewise, no restrictions for HbA1c or anti-diabetic treatment were used. Sensing data was collected continuously in the background on the phone to the extent the phone's OS allowed for this. Only participants who provided written informed consent were included. Participants received a gift certificate compensation worth DKK 500 (66 EUR) upon completion of the study, i.e. by participating in the exit group interview.

7 RESULTS

Table 2 shows the demographics of the recruited patients. 14 participants were recruited and enrolled in the study (step 1), 12 completed the system use and assessment of usability and usefulness (steps 2+3), and 10 participants

[5]This study was conducted during the COVID-19 lock-down, and all contact to study participant had to be minimized.

ID	Sex	Age	YwD	Days	Phone	Interview
P1	F	71	27	125	iOS	✓
P2	M	48	15	58	iOS	✓
P3	M	67	10	41	iOS	✓
P4	F	65	16	108	iOS	✓
P5	M	71	25	104	iOS	✓
P6	M	73	N/A	7	iOS	–
P7	F	44	1	14	Android	✓
P8	M	71	20	88	iOS	✓
P9	M	64	N/A	3	iOS	–
P10	M	69	12	110	iOS	✓
P11	F	67	8	38	iOS	✓
P12	M	71	6	124	iOS	✓
Overall	4/8 (F/M)	65 ± 9.3	14 ± 8.3	68 ± 46	11/1 (i/A)	10/12 (83%)

Table 2. Participants demographics. YwD: Years with T2D. Days: Days active in the study.

participated in the individual and group interviews (steps 4+5). The two drop-outs were due to technical issues with installing and running the app on their phones. Two participants (P6, P9) completed steps 2+3 but did not participate actively in using DiaFocus for very long (less than a week) and did not respond to the invitation to participate in the interviews in steps 4+5. As shown in Table 2, the participants on average used DiaFocus for 68 days but with significant variations between participants (±46 days) – some used it significantly longer than expected (over 100 days), while other used it significantly less.

Table 3 shows the number of data points collected during the feasibility study. More than 2600 data points were collected over a period of 5 months. As shown in Table 1, data collection includes both sensed (S) and patient-reported (PR) data. Automatically sensed data include step count, and device and battery characteristics. Patient-reported data include surveys (on lifestyle, well-being, emotional distress, sleep quality, depression, anxiety, etc.) and self-reported glucose measures, weight, alcohol intake, and the number of cigarettes smoked.

Due to new privacy restrictions in the Apple App and Google Play Store, the use of location was no longer allowed, if not used actively in the app. And since DiaFocus does not actively use location but merely samples it in the background, the measures on location, weather, and activity classification had to be disabled during the feasibility study.

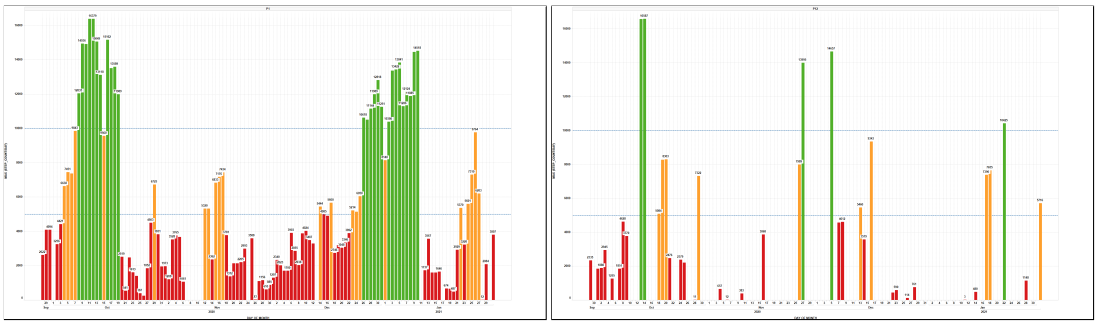
7.1 Automatically Collected Data

Table 3 shows the total number of automatically collected data; step counts, device information, and battery status. We observe a high spread in the amount of data collected across each participant, which partly reflects the different levels of engagement in terms of the length of use, as shown in Table 2. For example, P1, P4, P5, P10, and P12 used DiaFocus for more than 100 days and hence have a high number of e.g., step count data. As an illustration, Figure 9 shows the step count events for P1 and P12 over more than 100 days of sampling. Figure 9 also illustrates the color coding used on the home screen of the DiaFocus app (Figure 7a).

However, in order to investigate if sensing takes place automatically, it is relevant to investigate the so-called 'coverage' percentage, which is a relative measure that shows how much data was actually collected as compared to what is expected. In this case, coverage is calculated based on step count events, which are expected to be collected daily. Table 3 shows the coverage for each participant. We observe a high spread (SD on 32%) on the

Patient	Survey	Blood Glucose	Weight	Alcohol	Cigarettes	Step Count	Device	Battery	Cov. %
P1	51	212	9	–	–	232	46	46	92%
P2	14	17		2	–	24	17	18	33%
P3	21	–	3	3	–	9	5	5	22%
P4	57	3	3	–	–	104	25	25	56%
P5	52	27	1	–	–	88	18	18	41%
P6	3	1	1	2	–	1	1	1	100%
P7	24	–	92	93	92	242	55	152	93%
P8	24	18	6	5	3	77	18	19	40%
P9	2	–	–	–	–	18	8	18	100%
P10	54	21	13	3	–	106	30	32	40%
P11	9	1	1	1	–	7	4	4	13%
P12	34	6	5	–	–	97	23	29	33%
Total	345	306	135	109	95	1007	252	369	–
Average	28.75	34.00	12.27	15.57	47.50	77.46	19.38	28.38	55%
SD	20.43	67.43	26.72	34.17	62.93	81.93	16.73	39.39	32%

Table 3. Overall number of patient-reported and sensed data points collected per patient. Cov.: Coverage. SD: Standard deviation.



(a) (b)

Fig. 9. Step count events automatically collected for (a) P1 and (b) P12. The color coding is: Red - below 5 000 steps; yellow – between 5 000 and 10 000 steps; green above 10 000 steps.

coverage rate across participants which reflects that the DiaFocus app did not always run in the background and was collecting data. The step counts for P1 and P12 in Figure 9 illustrates the difference between a coverage of 92% and 33%, respectively.

By comparing the number of self-reported data (e.g., surveys) with the automatically collected data in Table 3, we see that there is a correlation between the two types of data; basically, if the user engages with the app for self-reporting, it also collects data automatically. This is due to that all (except P7) are using iPhones (see Table 2) and iOS only enable data collection if the app is running. If the app is closed, no data is collected.

	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	Total
B1 - Life Style Information	11	0	11	13	0	11	0	17	13	0	11	0	87
B2 - Emotional Distress	40	14	20	74	68	2	21	30	-	66	6	56	397
B3 - Well-being	40	15	30	75	65	5	25	35	5	65	15	45	420
B4 - Diet & Exercise	14	6	10	28	26	0	8	12	0	26	4	20	154
B5 - Blood Glucose	27	5	3	12	14	0	16	8	0	15	0	3	103
C - Area of Concern	–	–	–	–	–	–	–	–	–	–	–	–	0
D1 - Food Behaviour	–	–	–	–	–	–	–	–	–	–	–	–	0
D2 - Sleep Quality & Patterns	–	–	–	–	–	–	17	–	–	–	–	–	17
D3 - Depression & Anxiety	–	–	–	–	–	–	14	–	–	–	–	–	14
D4 - Medication Behaviour	–	–	–	–	–	–	–	–	–	–	–	–	0
Total	132	40	74	202	173	18	101	102	18	172	36	124	1192

Table 4. Overall number of questions in surveys answered per participant.

7.2 Self-reported Data

Self-reported data include surveys, blood glucose, weight, alcohol consumption, and the number of cigarettes smoked per day. Since DiaFocus focused on adaptive assessment, each patient reports different data depending on their focus areas and their answers to the surveys, as outlined in Section 4. This adaptation as unfolded in the study is evident from Table 3. For example, P1 was focusing on measuring and controlling her blood glucose and hence reported a lot of data on this and none on the other parameters, whereas P7 focused on lifestyle and hence reported on weight, alcohol, and cigarettes and not on blood glucose.

7.2.1 Surveys. The participants answered a total of 345 surveys comprising 1192 questions averaging to 100 questions answered per participant over the course of the study. Table 4 shows the number of questions answered by each participant divided into the different types of surveys shown in Figure 4. The B-type of surveys (B1–B5) were issued on a regular basis (weekly, bi-weekly, and monthly) to all participants throughout the study and hence answered by all. The D-type of surveys were only triggered based on answers in the B-type of surveys. For example, the survey on 'Sleep Quality' (D2) would only be shown if the participant reported problems with sleeping in the well-being survey (B3) and the 'Depression & Anxiety' (D3) survey would be triggered by reporting this as a problem in the 'Emotional Distress' (B2) survey. Table 4 shows that only one patient (P7) reported such problems and were hence shown the D2 survey twice and the D3 survey once. No participants reported issues with food or medication, and the D1 and D4 surveys were hence never issued.

7.2.2 Blood Glucose. Information about blood glucose was collected both via the blood glucose survey (B5) which most of the patients filled in (see Table 4), as well as via self-reported glucose measures done using the BGM. The data collected from P1 can work as an illustration. P1 had control of blood glucose as her main 'area of concern' and hence used DiaFocus for the collection and visualization of blood glucose data. As shown in Table 3 and Table 4, she is the one who has self-reported most blood glucose data points (212) and has filled in most B5 surveys (27)

Figure 10 shows an overview of the self-reported blood glucose data from P1, with each data point color-coded according to the color-coding used in DiaFocus. Figure 10 illustrates that P1 consistently self-reported glucose data throughout the study period with only very few gaps. During the interview, P1 stated that her target was to do two measurements per day and looking at the data she has been reporting 1.7 measurements per day on average. This case illustrates that collection of blood glucose data in DiaFocus is a viable design for a 71-year-old woman.

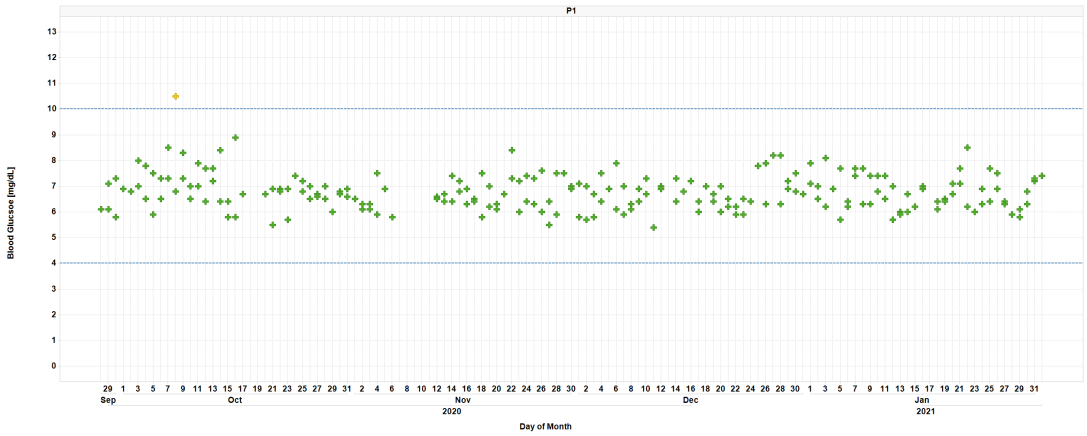


Fig. 10. Blood glucose data as reported by P1.

7.2.3 Alcohol and Cigarettes. Table 5 provides an overview of self-reported alcohol and smoking habits. Four out of 12 participants reported alcohol consumption and two reported smoking. All alcohol consumption was less than 7 units per week (the recommended limit for women in Denmark). The data collected from P7 can work as an illustration. P7 focused on lifestyle and were consistently reporting on smoking and alcohol consumption. Figure 11 shows the self-reported number of cigarettes per day for P7. Figure 11 also illustrates the color coding used in DiaFocus (see Figure 7(a)). The color-coding algorithm looks at the number of cigarettes within a time window of the last 6 days, and if the average of the latest three days is less than the average of the first three days (smoking is reduced), then the color is yellow, otherwise, it is red.

7.3 Perceived Usefulness and Usability

Participants' attitudes and reflections on the usefulness and usability of the system were assessed using the CUMACF questionnaire (see Appendix A) and from post-study interviews ($N = 10$). This section describes the key results and findings organized by the CUMACF categories of (i) health expectancy, (ii) effort expectancy, (iii) social influence, (iv) facilitating conditions, and (v) behavioral intention. The results from the CUMACF questionnaire are shown in Appendix C.

7.3.1 Health Expectancy. Health expectancy investigates the degree to which an individual believes that using the system will help attain gains in health. The CUMACF results are shown in Figure 12. The results show that participants were mostly neutral as to whether DiaFocus would be useful in managing their diabetes health and keeping track of disease symptoms, and the majority of participants found that the app would not help to reduce disease symptoms or complications.

When asking about health expectancy during the interviews, the feedback from most participants was that they have had T2D for so many years ($\mu = 14$), that DiaFocus would not provide any added value to managing their diabetes symptoms and complications. Most argued that they had already built up routines and behavioral patterns to manage their disease and they did not feel that the system would provide them with major improvements in their health. However, most participants also highlighted that the system would be useful in the early years after diagnosis and hence for other newly diagnosed T2D patients and that they appreciated the simple overview of their data such as activity, alcohol, and blood glucose in the app. As expressed by one participant: *"I think Diafocus could help people create good habits and retain them. [...] The tricky part with diabetes is that you don't*

	Alcohol			Smoking	
Patient	Drinking?	Frequency	Units	Smoking?	Frequency
P1	–			–	
P2	–			–	
P3	–			–	
P4	✓	occasionally	<7	–	
P5	–			–	
P6	–			–	
P7	✓	occasionally	<7	✓	daily
P8	✓	daily	<7	✓	occasionally
P9	✓	occasionally	<7	–	
P10	–			–	
P11	–			–	
P12	–			–	

Table 5. Alcohol consumption and smoking status per patient.

feel the long-term consequences of not managing your disease properly until many years after." (P3) This view on DiaFocus was confirmed by the participant who was diagnosed with diabetes less than one year before using the app (P7), who found it useful in understanding her disease better: *"I have a hard time confronting my GP when I don't feel understood about my disease. I think the app can help me with [the data and information] I need to convince him to listen."* (P7).

7.3.2 Effort Expectancy. Effort expectancy assesses the degree to which an individual believes that ease is associated with the use of the system, and is a measure of perceived ease-of-use or usability of the system. Figure 13 shows the CUMACF results, showing that a majority of the participants were satisfied with the overall ease-of-use of DiaFocus and found it easy to use and easy to learn to use. However, fewer participants found the UI to be good and the information to be clear, and a majority found that DiaFocus did not have all the functionality needed.

During the interviews, the participants added more nuanced insights. Overall, participants appreciated the simple design, ease of interaction, and logical navigation between the different features. Participants found the health status and data visualization useful, as expressed by P10: "*I like to check the app daily to have some control points for seeing how I am doing with my diabetes*". Participants highlighted the ability to report and see their data in an accessible manner as an important feature of the app. Particularly, some participants appreciated the ability to see patterns and relationships between their different types of data, including the overview provided by the color coding of their different health statuses. Some participants did, however, have some problems reading the data visualization and wanted more explanation of the color coding and the linkage to the collected data. As expressed by P2: "*I'm missing indicators on the landing page to give a more thorough understanding of how my numbers impact my health. What does moving from [a] green to [a] yellow color indicator for diabetes management mean?*".

When investigating that several participants (41%) did not think they would be proficient in using DiaFocus, they argued that the UI on a mobile phone was too small and they had problems hitting the right buttons and typing in text. Moreover, during the study we found that many participants had problems typing in their username and password, and were often blocked by the system after 3 unsuccessful attempts. Others just found using an app on the mobile phone as "*too cumbersome*". The majority (58%) of the participants expressed that DiaFocus did not have the functionality they would expect. When asking about this, it turned out to be linked to the findings

above, namely that the participants found the functionality to be most useful for people who had not had diabetes for a long time. For example, as expressed by P8 who has had diabetes for 20 years: "*I don't think all the data in the app is relevant to me, as I mostly focus on blood glucose. New people with diabetes might find it more relevant.*" Moreover, several patients expressed that keeping track of medication and physical activity beyond step counting would be important features to add to DiaFocus.

7.3.3 Social Influence. Social influence assesses the degree to which an individual perceives that important others believe s/he should use the system. As shown in Figure 14, the majority of the participants did not answer these questions. These results reflect the study design and the fact that no HCPs were involved in this feasibility study. None of the participants involved their own GP in the use of DiaFocus and the data collected, and very few involved their spouse or others in the use of the app due to the limited time span of the study.

The interviews revealed that many participants would find the DiaFocus system motivating if put into regular use in their diabetes treatment and care. As put by P4 who has had diabetes for 16 years: "*It is nice that the app collects and presents my data to me — it has kept me motivated at some points to keep going with what I need to*". Participants argued that the app would motivate them to stick to healthy habits and follow the advice and plans from the HCP. They pointed to the support for recurrent focus on diabetes management via the surveys, the collection and visualization of data, and the ability to create personalized plans and focus areas together with their HCP as the main features in DiaFocus supporting this.

7.3.4 Facilitating Conditions. Facilitating conditions assess the degree to which an individual believes that an organizational and technical infrastructure exists to support the use of the system. As shown in Figure 15, the majority of the participants agreed that the necessary organizational and technical resources would be available for DiaFocus. During the interviews, most participants expressed that they had a sufficiently new smartphone to run the system and only one participant had a phone that was too old. They also argued that the app was a 'standard' app like many others and hence straightforward to install and use. Despite the need for upgrading the app during the study and the need for re-login, most participants found that there was sufficient support for the system. However, some participants (25%) still found the support lacking and had problems upgrading the app, which again was leading to data loss.

7.3.5 Behavioral Intention. Behavioral intention assesses the degree to which an individual intends to use the system in the future, based on the experience of using it now. This is only a single question and represents the overall assessment of intended use. As shown in Figure 16, half of the participants would use the system in the future if available, while 17% would not.

When asking about the future use of DiaFocus and such kind of mHealth technologies, we found that all participants ($N = 10$) were positive towards using a system like DiaFocus for the management of their diabetes in the future. 70% ($N = 7$) already used some health monitor devices such as smartwatches, and 80% ($N = 8$) were positive towards using a continuous glucose monitoring (CGM), if relevant to their diabetes. 90% ($N = 9$) were positive towards their health and behavior data being collected and shared with others, as long as it is for health purposes. 30% ($N = 3$) expressed concerns about health and behavior data potentially being abused.

8 DISCUSSION

The main focus and contribution of DiaFocus is its adaptive approach to the psycho-social assessment of patients with T2D as part of the iPDM treatment process, which has shown to improve the treatment of diabetes by lowering long-term blood sugar levels (HbA1c) [30, 43, 44]. In this section, we will discuss the lessons learned from this study. First, we will discuss the use of semi-automatic mobile sensing technology in the design of mHealth diabetes management systems, and then how the use of this type of technology in DiaFocus supports the adaptive approach to the psycho-social assessment of patients with T2D as part of the iPDM treatment process.

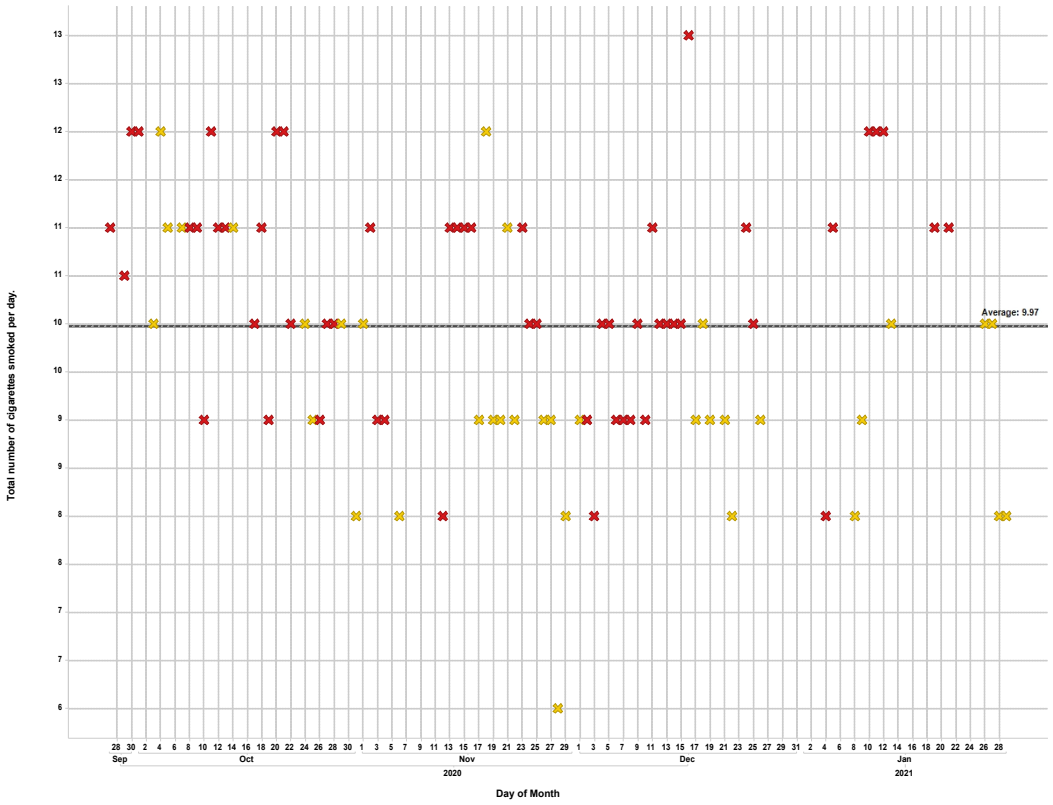


Fig. 11. Smoking for P7. Number of smoked cigarettes per day color-coded according to the algorithm used in DiaFocus: Red: Smoking is stable or increasing. Yellow: Smoking has been reduced.

Then we will discuss the participants' perceived usefulness and usability of the system, and finally, we will discuss the strengths and limitations of this research.

8.1 Mobile Sensing for Diabetes

As shown in Table 1, DiaFocus supports the collection of a wide range of measures – both automatically sensed and patient-reported data. The study showed how such data was collected consistently over the duration of the deployment, as shown in Table 3. Moreover, the software architecture of DiaFocus is designed to be highly extensible and enables easy inclusion of new measures. As such, this architecture supports the adaptation of different measures in diabetes management. For example, it would be possible to include other patient-reported measures such as surveys and self-reported data items (like blood pressure) to DiaFocus. Sensor-based measures can be added via the CAMS framework, which includes access to data stored in Apple Health, for example. This would enable the collection of health data from other apps or wearable devices, like activity trackers collecting data on steps, sleep, and activity – data types that were mentioned by the participants to be useful to add. Moreover, CAMS also enables integration to other wearable and medical devices, and data from CGMs could be added to DiaFocus. Hence, the software architecture of DiaFocus is rather flexible and extensible, and the DiaFocus system could be extended to include a wide range of novel assessment parameters in its adaptive

assessment approach. As such, DiaFocus could potentially also be useful in enabling data collection within clinical trials by collecting patient-reported, behavioral, lifestyle, and physiological data in trials on pharmaceuticals or medical devices.

However, during the deployment of DiaFocus we had to disable the collection of location and activity data due to new stricter privacy policies from Google and Apple. This was a significant change to the study protocol since the collection and analysis of activity levels (such as walking, running, and biking) are important to get an insight into the metabolic status of a person with diabetes, and because studies have shown significant correlations between mobility patterns and depression, which was part of the psycho-social assessment in DiaFocus. We found that in mobile sensing systems, there is a constant need for adjusting the design and the sampling of an app so that it complies with the rules and policies of Apple and Google. As such, these companies put significant constraints on what can be done in mobile sensing for health.

With respect to background data sampling, we found big differences in 'sampling coverage' as shown in Table 3. Mobile sensing is dependent on the ability to keep the app running in the background of the phone's OS, and there are big differences between the two OSs (iOS and Android) and their different versions, with a tendency that the newer OS versions more aggressively killing the app in the background. Moreover, when investigating app usage during interviews, we also found that many participants were 'swiping' the app out of memory once they have finished using it, thereby terminating it. In mobile sensing, these problems are well-known – especially on iOS – and are the reason why most mobile sensing frameworks only target Android [45]. However, in this study, a vast majority of the participants (91%) used iOS, and the fact that CAMS – and hence DiaFocus – supports data collection on iOS is still a major advantage to the DiaFocus architecture.

8.2 Adaptive Psycho-Social Assessment in Diabetes

As outlined in Section 2, understanding and addressing the patient's psycho-social state is increasingly recognized as a fundamental part of diabetes treatment, while most mHealth technologies focus on the more physiological part of diabetes in terms of blood sugar management sometimes in combination with tracking food consumption and/or physical activity. In contrast, the approach used in DiaFocus is to start with an assessment of the patient's psycho-social situation including lifestyle issues, general well-being, sleep quality, and symptoms of diabetes distress, depression, and anxiety using standardized and validated tools, as recommended by the American Diabetes Association [72] (see also Section 2.2). The assessment of blood glucose levels, dietary, and behavioral aspects are dynamically added on top of this. As shown Table 4, this study demonstrated that psycho-social data was collected consistently as the different B-type of surveys were issued to the participants. During the interviews, the participants generally expressed a positive attitude towards filling in the surveys on psycho-social issues like well-being, distress, mood, etc. They appreciated the concept and were positively anticipating their HCP to be able to include such topics during future consultations. As said by P12: "*I like to share my thoughts and opinions about diabetes through the surveys*". Furthermore, several participants felt it nice to be asked about their feelings and thoughts about living with diabetes as opposed to the more traditional focus on clinical measures such as blood glucose values, cholesterol, weight, etc. As stated by P11: "*[I feel that] it's not me as a person who're in focus [during consultations], but rather my diabetes disease. I want that to change — and maybe the app can help do that*". Some participants, however, also expressed mixed expectations as to whether their HCP would have the necessary time, training, and skills for handling conversations about the psycho-social aspects of living with diabetes as a chronic disease.

As outlined in Section 4, DiaFocus does data collection and assessment in an adaptive and personalized manner. In many survey tools for patient-reported data, patients need to fill in long and tedious questionnaires which put a significant burden on them. For example, the original Problem Areas in Diabetes Questionnaire (PAID) and Short Form (SF) questionnaires comprise 20 and 36 questions, respectively. This leads to reduced patient

engagement and lack of compliance in filling in questionnaires [11]. In DiaFocus, surveys are issued to the user in an adaptive manner where surveys are only shown if needed. Moreover, data collection was also enabled or disabled, as needed. In the study, this adaptive nature of DiaFocus is apparent when comparing P1 and P7. P1 had picked 'monitoring blood glucose' as her main focus area, and was able to report blood glucose levels several times daily, as shown in Figure 10. P7, on the other hand, had picked 'food, eating or alcohol habits' and 'quit smoking' as her focus areas, and was able to report weight, smoking, and alcohol consumption as shown in Table 3, Table 5 and Figure 11. Moreover, since P7 was reporting issues with sleep and depressive mood in the B-type of surveys, the sleep (D2) and depression (D3) surveys were issued to her. Enabling such adaptive assessment was a strength in the study; P1 had a clear interest in closely monitoring her blood glucose level on a daily basis and was hence motivated to perform the annoying and slightly painful procedure of making a finger-prick test with a BGM. In contrast, P7 had no need for monitoring blood glucose levels and was spared this annoyance. P7 was, however, able to track weight, smoking, and alcohol consumption, which were useful for her – something which was useless to P1 who neither smoke nor drink alcohol.

One interesting observation is, however, that only one participant (P7) accessed the D-type of surveys, which are designed to collect more specific information on a particular 'area of concern'. And since no data is collected from D1 or D4 surveys, apparently no participants found food or medication any concern. This is quite contrary to most clinical guidelines which have a significant focus on exactly food behavior and medication compliance [19]. When analyzing the data, we found a few reasons why these surveys were not accessed by the participants. First, the D surveys were only triggered if the participant stated that food, sleep, depression, or medication were of 'moderate' or 'high' importance in the C survey (see Appendix B.3). And since the C survey was only triggered once per month (see Table 1), most participants were hardly exposed to this survey during the study period. Second, during the interviews we asked the participants; *"Is there any specific area of diabetes that your doctor has asked you to focus on?"*. This question was designed to investigate 'areas of concern' and to see if they match the findings from DiaFocus. Interestingly, none of the participants mentioned food, depression, or medication as something their doctor has asked them to look for. Half of the participants answered "none" to this question and the rest mentioned topics like 'losing weight', 'stable blood sugar levels', 'exercises', and 'diet'. All of these topics were covered by the more regular B surveys.

In summary, when looking at the usage patterns and results from the study, we see a large heterogeneity in terms of selected focus areas and collection of data. Hence, even in this relatively small study, we see how DiaFocus is able to support adaptation in the assessment of both psycho-social, physiological, and behavioral data. However, we found that the D surveys were filled in too seldom and that there is a need to adjust the triggering of these surveys to be more frequent.

8.3 Usefulness and Usability of mHealth Technology for Diabetes

In terms of perceived usefulness for the long-term management of diabetes (health expectancy), the study showed mixed results. Overall, participants provided very positive feedback on the ability to choose personal focus areas and make corresponding plans. As put by P2: "*Even after 15 years [of being diagnosed with diabetes] my focus changes – so it's very useful for me to use the app to put it in writing and make concrete plans for how to act*". Most participants anticipated that the feature of choosing a focus area and making a plan when sitting in the consultation with their HCP would potentially impact the way they communicate with their HCP – irrespective of time since diagnosis. This selection of a focus area combined with the ability to track and visualize different health parameters over time was considered a useful feature in DiaFocus. The data from the study also seems to back this. For example, P1 had selected 'monitoring blood glucose' as a focus area and she was able to collect daily BGM readings and to keep her blood glucose levels within the target range over the entire study period of 125 days, as shown in Figure 10. Moreover, the focus on assessing psycho-social state and using this assessment

during the consultations with the HCP was considered very useful, if the HCP would have the time and expertise to review such assessments. However, since none of the participants shared the data with their HCP during the study, this was merely perceived usefulness.

Looking across participants, we found that participants who had been diagnosed with diabetes for a long time did not find DiaFocus as useful as the newly diagnosed participants. The experienced participants argued that they had already built healthy routines around their diabetes management. Education and establishing good routines is the first step in the diabetes management cycle and is an established pillar of any type 2 diabetes treatment pathway [47]. Hence, based on this study, it seems like DiaFocus may be most useful to newly diagnosed people with T2D, which is also the time when such an intervention is likely to have the greatest effect.

In terms of usability (effort expectancy), participants generally expected DiaFocus to be easy to use and that the necessary technical and organizational infrastructure (facilitation conditions) would be in place. The main feedback to the design of DiaFocus was to add support for medication and activity tracking, and a better explanation of the logic behind the color-coding, which would enable users to understand what behavior would improve on the colors. For example, none of the participants were aware that if they just smoked a single cigarette or if their Body Mass Index (BMI) was too high, their 'lifestyle' color code would never become green. If DiaFocus is deployed in clinical use as part of an iPDM setup, it would be important to set up a patient support and education program, which could help the patients to use and navigate the system and address such questions.

One central observation during the study was, however, that some participants had significant problems with using the smartphone as a platform for DiaFocus. Things that had nothing to do with the DiaFocus app – like creating an App Store account, downloading and installing an app, remembering and typing in username and password, and typing text on a small keyboard – proved to be quite large obstacles for especially the elderly participants. From a more theoretical point-of-view, it is often argued that the smartphone makes a perfect platform for health technology (mHealth) due to its strong technical resources in terms of computing, sensing, and networking combined with its ubiquitous availability amongst most users worldwide. However, this study shows that this may be the case, but there are still many – especially elderly – users, who find it hard to use the advanced features of a smartphone and for who this kind of advanced mHealth technology is hard to use.

8.4 Strengths

This study reports from an extensive user-centered analysis, design, development, and evaluation process which has involved a large number of stakeholders with deep insight into diabetes and health technology. The participants were a heterogeneous group of people, comprising patients with T2D, diabetes researchers, psychologists, computer scientists, software engineers, and a wide range of HCPs including GPs, senior and junior diabetes consultants (MD), nurses, rehabilitation therapists, and dietitians. The design process was done over an extensive period of time (24 months) and had a large number of iterations, thereby incorporating a lot of feedback from the stakeholders. Therefore, the results in terms of the DiaFocus system and its deployment in the socio-technical use as part of the iPDM treatment approach embody solid and deeply rooted experience in how to manage and treat T2D in primary care.

8.5 Limitations

The study reported in this paper is a single-arm feasibility study and does not provide any clinical evidence on the health efficacy of the use of DiaFocus as part of the iPDM process. Moreover, the study is limited in the number of participants and their inconsistent use of DiaFocus with some participants using the system for more than 100 days, whereas some using it for less than a week. The study did not evaluate the entire iPDM cycle (Figure 3) and only focused on steps 1–3, with a main focus on assessing the feasibility of using DiaFocus during step 3. The amount of data collected – both automatically and self-reported – was sparse and the present study does not

allow for investigating potential correlations between mobile sensing data and health outcomes. Evaluation of DiaFocus during the entire iPDM cycle is the focus of an ongoing clinical study.

9 CONCLUSION

Type 2 diabetes (T2D) is a large disease burden for society and for the individual, management of diabetes is a complex and long-term challenge. It is well-known that the early establishment of a healthy lifestyle and monitoring of blood glucose and other physiological parameters is key to the management of diabetes, while less emphasis has been on improving patient-physician communication and addressing the psycho-social context of diabetes management for the individual.

This paper has presented the DiaFocus system, which is a mobile sensing technology for the long-term management of diabetes. DiaFocus is designed to support the iPDM diabetes treatment process, which has been shown to significantly improve the glycemic outcome for people living with T2D. DiaFocus implements an adaptive assessment approach that takes an assessment of the patient's psycho-social state as the outset for further adaptive assessment of relevant physiological (e.g., blood glucose), lifestyle (e.g., smoking), behavioral (e.g., step count), contextual (e.g., location or noise), and self-reported (e.g., well-being survey) data. DiaFocus is designed to be a data-driven dialogue tool to be used between the patient and the HCP as part of the iPDM treatment cycle, which can be personalized to the individual patient focusing on specific areas of concern.

The design of DiaFocus was based on an in-depth user-centered design process, which spanned 24 months and involved a wide range (30+) stakeholders including patients, medical doctors, GPs, nurses, dietitians, physiotherapists, and social care workers. The software architecture of DiaFocus builds on a set of flexible and extensible software components for mobile sensing and collection of patient-reported data. This architecture allows for the flexible addition of new sampling measures both in terms of collection of data from wearable and medical devices, from the phone, as well as incorporating new surveys and questionnaires.

The DiaFocus system was subject to a technical feasibility study involving 12 participants, who used the system for 68 days on average. Overall, the participants reported that based on their experience with using DiaFocus, they would expect it to be useful and easy to use as part of their treatment if embedded into the iPDM treatment cycle. Most participants engaged actively in using the system and created personalized focus areas which adapted to the collection of measures. The study also found that DiaFocus were perceived as mostly useful for early diagnosed patients, and we found that some of the elderly patients had problems using the smartphone for such advanced mHealth applications.

Based on the extensive design process, the software architecture, and the findings from the feasibility study, we find that DiaFocus shows potential for supporting the iPDM treatment process, which again could lead to improved treatment of T2D patients. We are currently running a clinical trial to investigate this. Due to its extensible software architecture which allows for easy addition of new sensing modalities, including patient-reported outcome data, we also find that DiaFocus could be useful for data collection within clinical trials on pharmaceuticals or medical devices.

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A CUMACF QUESTIONNAIRE

No.	Target	Statement
Health expectancy (HE) : The degree to which an individual believes that using the system will help him/her to attain gains in health outcome.		
HE1	Usefulness	In general, I would think that DiaFocus is useful for managing my diabetes.
HE2	Adherence	I would use DiaFocus as often as recommended, i.e., daily.
HE3	Behavior	Using DiaFocus would help me to keep track of my disease symptoms and treatment.
HE4	Health	Using DiaFocus helps me reduce my disease symptoms.
HE5	Efficiency	Using DiaFocus helps me to reduce disease symptoms faster and efficiently.
HE6	Quality	Using DiaFocus improves the quality of my treatment.
HE7	Safety	Using DiaFocus reduces the risk of me having complications due to my diabetes.
Effort Expectancy (EE) : The degree to which an individual believes that ease is associated with use of system.		
EE1	Usability	Overall, I would be satisfied with how easy it is to use DiaFocus.
EE2	Understandable	My interaction with DiaFocus would be clear and understandable.
EE3	Learning	It would be easy for me to learn to use DiaFocus.
EE4	Easy	I would find DiaFocus easy to use.
EE5	Skillful	I would be skillful at using DiaFocus.
EE6	Information Quality	The information I get from DiaFocus is clear and useful.
EE7	Interface Quality	The user interface is good when I use DiaFocus.
EE8	Pleasure	DiaFocus is comfortable to use.
EE9	Features	DiaFocus has the functionality I expect.
Social Influence (SI) : The degree to which an individual perceived that important others believe s/he should use the system.		
SI1	Health professionals	My therapist thinks that I should use DiaFocus.
SI2	Relatives	My family (e.g., my spouse) thinks that I should use DiaFocus.
SI3	Friends & Peers	My friends and colleagues think that I should use DiaFocus.
SI4	Society	I am expected to use DiaFocus as a patient in the Danish healthcare system.
Facilitating Conditions (FC) : The degree to which an individual believes that an organizational and technical infrastructure exist to support use of the system.		
FC1	Resources	I would have the resources necessary to use DiaFocus, such as a smartphone.
FC2	Knowledge	I would have the knowledge necessary to use DiaFocus.
FC3	Support	Someone would be available to help with technical issues.
Behavioural intention (BI) : The degree to which an individual intends to use the system.		
BI	Plan	I plan to use DiaFocus in the coming months.

B SURVEYS

B.1 B1 – Life Style Information

ID	Question	Answer Format
B1-1	What is your weight?	0–300
B1-2	How many days during the last week have you exercised for at least 30 minutes?	0, 1-2, 3-4, 5-6, 7
B1-3	How many days during the last week have you followed a healthy diet?	0 | 1-2 | 3-4 | 5-6 | 7
B1-4	Do you drink alcohol?	yes/no
B1-5	How often do you drink alcohol?	occasionally / every day
B1-6	Alcohol consumption frequency in units pr. week?	<7 | 8-14 | >14
B1-7	Do you smoke cigarette?	yes/no
B1-8	How often do you smoke cigarettes?	occasionally / every day
B1-9	How many cigarettes do you smoke?	<1 | 1-2 | 2+ packs / day
B1-10	Do you usually smoke your first cigarette within 30 minutes of waking up in the morning?	yes/no
B1-11	Are you treated with oral tablets to control your blood sugar?	yes/no
B1-12	Are you treated with insulin to control your blood sugar?	yes/no
B1-13	Are you treated with other glucose lowering injections to control your blood glucose?	yes/no
B1-14	How often do you monitor your blood glucose levels at present?	0-4 times pr. day
B1-15	In the past month, have you had any episodes with low blood glucose?	yes/no
B1-16	How often in the past month, have you had episodes with low blood glucose?	0 | 1-2 | 3-4 | 5-6 | 7
B1-17	Did you need assistance from others during any of these episodes of low blood glucose?	yes/no
B1-18	How often did you need assistance from others during episodes of low blood glucose?	0 | 1-2 | 3-4 | 5-6 | 7
B1-19	How many diabetes check-up visits have you had in the past year?	0-5

B.2 B2 – Emotional Distress

Instructions: *"For the upcoming questions, please consider which of the following diabetes areas are currently a problem for you?"*

Answer Scale:

- *Not a problem*
- *Minor problem*
- *Moderate problem*
- *Somewhat serious problem*
- *Serious problem*

ID	Question
B2-1	Feeling depressed when you think about living with diabetes?
B2-2	Feeling that diabetes is taking up too much of your mental and physical energy?
B2-3	Feeling overwhelmed by your diabetes?
B2-4	Feeling constantly concerned about food and eating?
B2-5	Feeling alone with your diabetes?
B2-6	Feeling "burned out" by the constant effort needed to manage diabetes?

B.3 C – Areas of Concerns

Areas of concern can be the following:

- *Food, eating or alcohol habits*
- *Monitoring blood glucose*
- *Managing high blood glucose*
- *Managing low blood glucose*
- *Improving exercise habits*
- *Stopping smoking*
- *My medications*
- *A diabetes topic not listed above*
- *Don't have a preference*

, and the importance the following:

- *Not at all*
- *A little*
- *Mildly*
- *Moderately*
- *Highly*

ID	Question
C-1	Next, we would like you to pick one area of diabetes care that you would like to talk to your doctor about.
C-2	If you would like to have a secondary area of diabetes care that you would like to talk to your doctor about, please choose below.
C-3	How important is it to you right now that you improve your primary area of concern?
C-4	If you decided right now to improve your primary area of concern, how confident are you that you will succeed?

B.4 D1 – Food behavior

Instructions: *"We now going to ask about some of the problems that you've had with food and eating."*
Answer Scale:

- *Never*
- *Rarely*
- *Sometimes*
- *Often*
- *Always*

ID	Question
D1-1	I can't find the time to make healthy meals.
D1-2	Dealing with food outside the home is difficult (eating at restaurants, eating at friend's houses, going to parties, eating at work).
D1-3	I eat food just because it is there.
D1-4	Sticking to my meal plan just seems to hard.
D1-5	It is difficult to avoid high fat foods.
D1-6	I eat when I am bored or stressed.
D1-7	My friends and family make it hard for me to stick to a healthy eating plan.
D1-8	I am hungry when I follow a healthy eating plan.
D1-9	I feel hopeless because I have tried and failed so many times.

B.5 D4 – Danish Medicine Adherence Scale

ID	Question	Answer Format
D4-1	Do you sometimes forget to take your medications?	yes/no
D4-2	People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your medications?	yes/no
D4-3	When you travel or leave home, do you sometimes forget to bring along your medications?	yes/no
D4-4	How often do you have difficulty remembering to take all your medications?	never / rarely / sometimes / usually / always
D4-5	How many types of diabetes medicine (prescribed) are you taking on a regular basis?	1 | 2-4 | 5-7 | >8
D4-6	Is there diabetes medicine you don't buy because it is too expensive for you?	yes/no
D4-7	Who takes care that you take your prescribed diabetes medicine?	me / spouse / another / pharmacy

C CUMACF QUESTIONNAIRE RESULTS

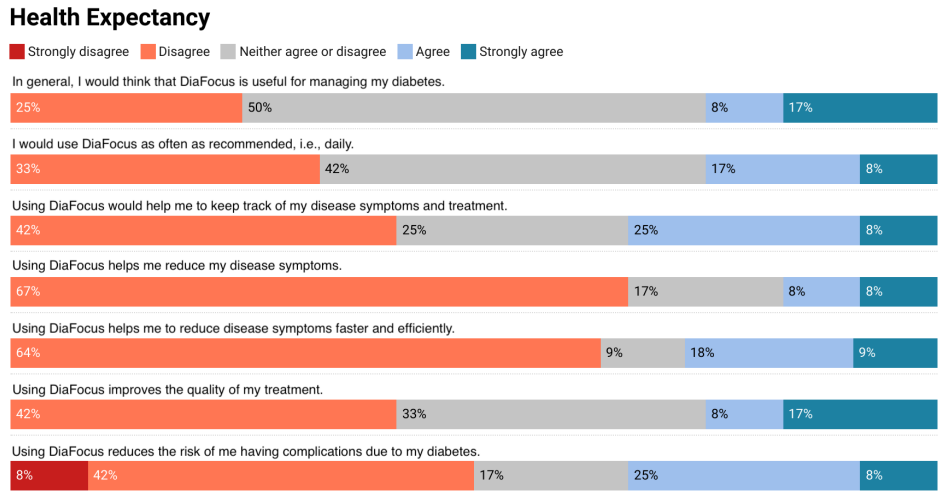


Fig. 12. Health Expectancy.

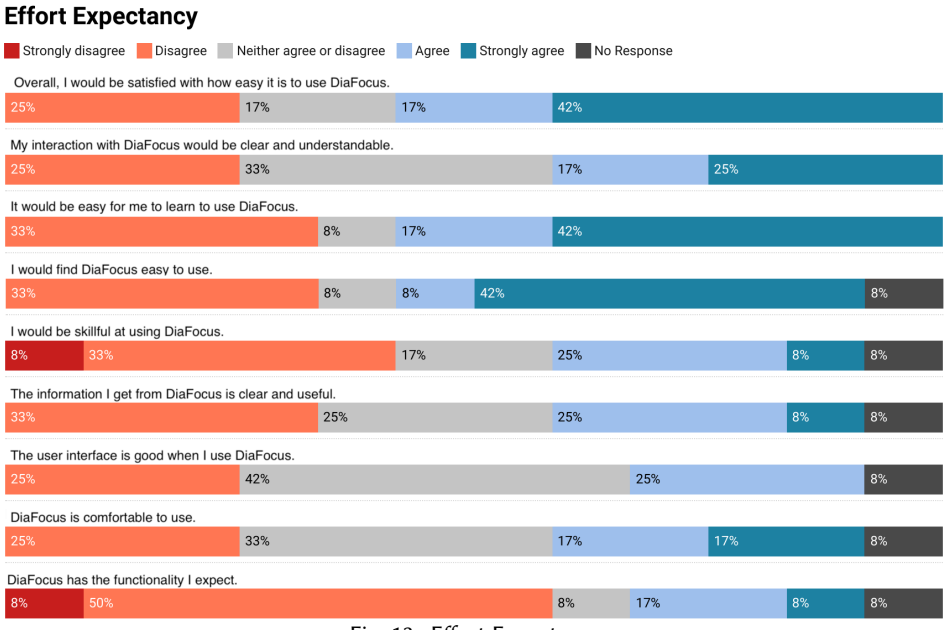


Fig. 13. Effort Expectancy

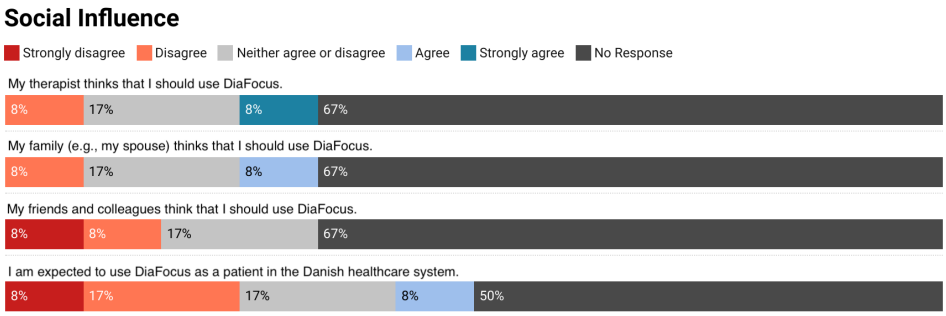


Fig. 14. Social Influence

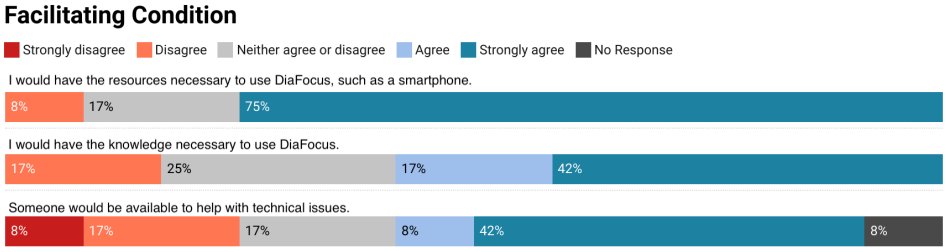


Fig. 15. Facilitating Conditions.

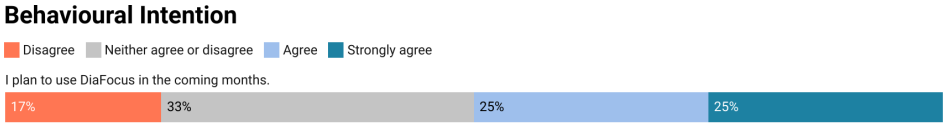


Fig. 16. Behavioural Intention.

D CLINICAL REPORT

The following pages contain an example of the report that the clinicians are using during consultations. It contains the following main sections:

- **Header** – containing basic patient information like name, social security number, etc.
- **Summary** – showing the status and progress for each clinical visit color-coded according to the same algorithms applied in the DiaFocus app.
- **Focus and Plan** – providing an overview of how the patient thinks he or she is progressing with the selected focus areas. Again color-coded into red ('bad'), yellow ('ok'), and green ('good').
- **Considerations** – highlighting which focus areas the patient is currently working on (e.g., 'Monitoring Blood Sugar'), how important this is to the patient, and how confident they are that this is progressing as it should.
- **Food Behavior** – showing the latest scores from the D1 survey.
- **Medicine Adherence** – showing the latest scores from the D4 survey (MA). The MA is a Danish survey, and the questions are hence only available in Danish (even though the report is also available in English, as shown below).
- **Well Being** – showing a historical overview of the WHO-5 scores from the B3 survey.
- **Sleep Quality** – showing the latest score from the D2 survey (PSQI).
- **Depression and Anxiety** – showing a historical overview of the HADS scores from the D3 survey.
- **Problem Areas in Diabetes** – showing a historical overview of the PAID scores from the B2 survey.
- **Blood Glucose** – visualizing a historical overview of blood glucose measures as either self-reported by the patient or collected from a BGM.
- **Lifestyle** – showing historical development for the measures on weight, alcohol, smoking, exercise, steps, and diet.

diacare

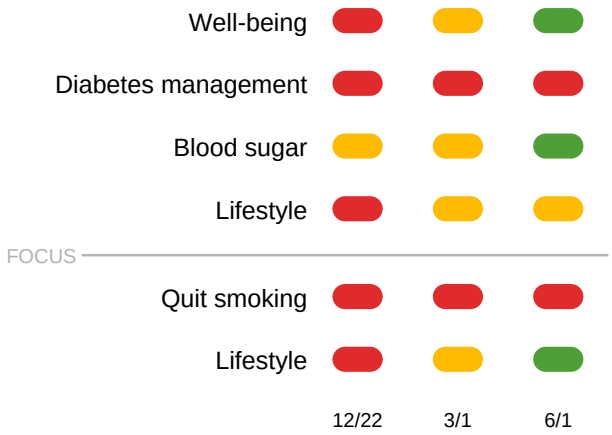
Patient Report
Report ID: REPORT_ID
Generated: 20/06/22

Full name
Jens Nielsen
CPR number
310585-1122
Sex
Male
Height
180cm

Phone number
+45 12345678
E-mail
jnls@1234.com
Status
Enrolled
Joined study
19/05/31

Next Consultation
20/06/01

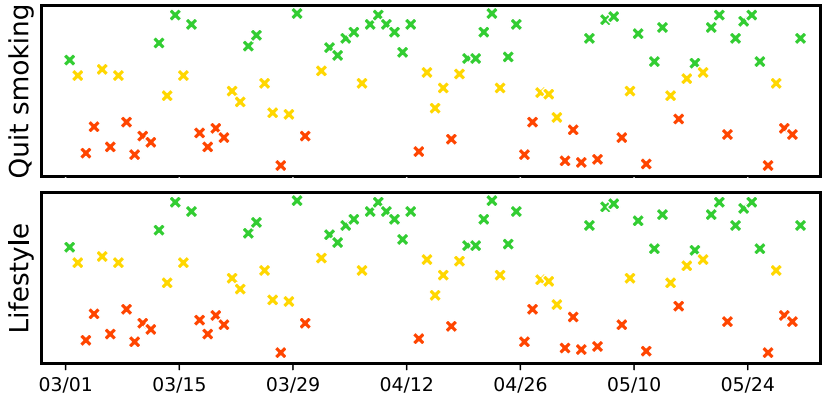
Summary



Focus and plan

PLAN

- Try to eat according to the ‘kostråd’
- Try to eat according to the ‘kostråd’, extra long table element expected to break automatically
- Go for a walk everyday after dinner
- Sign up to fitness team
- Try not to smoke before 11 am
- Try to eat according to the ‘kostråd’, extra long table element expected to break automatically
- Go for a walk everyday after dinner
- Sign up to fitness team
- Try not to smoke before 11 am
- Reduce daily cigarettes by 10



Considerations

Area	Importance	Confidence
Blood sugar	High	Low
Alcohol	Moderate	High

Food behaviour

RESPONSES 20/02/14

1: Always 2: Often 3: Sometimes 4: Rarely 5:Never

I can’t find the time to make healthy meals.	1
Dealing with food outside the home is difficult (restaurants, friend’s houses, parties, work).	1
I eat food just because it is there.	1
Sticking to my meal plan just seems to hard.	1

It is difficult to avoid high fat foods.	1
I eat when I am bored or stressed.	1
My friends and family make it hard for me to stick to a healthy eating plan.	1
I am hungry when I follow a healthy eating plan.	1
I feel hopeless because I have tried and failed so many times?	1

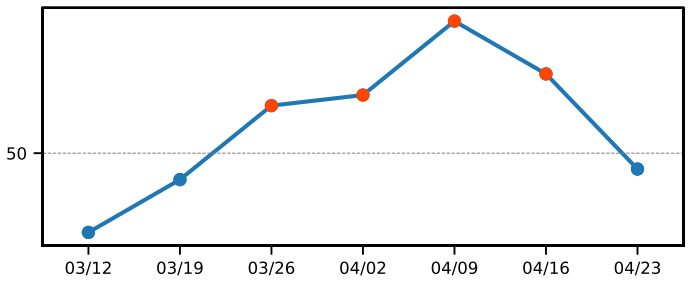
Medicine Adherence (MA-4)

RESPONSES 20/06/01

Glemmer du somme tider at tage din diabetes medicin?	Ja
Nogle mennesker får ikke altid taget deres medicin af andre grunde end fordi, de glemmer det. Hvis du tænker på de sidste to uger, har der så været dage, hvor du ikke tog din medicin?	Nej
Glemmer du somme tider at medbringe din medicin, når du rejser eller tager hjemmefra?	Nej
Hvor ofte har du vanskeligt ved at huske, at tage al din Sjældent diabetesmedicin?	Ofte
Hvor mange typer diabetesmedicin (receptpligtige) skal du tage fast?	Ingen
Er der diabetesmedicin du ikke køber, fordi det er for dyrt i forhold til din økonomi?	Ja
Hvem sørger for, at du får taget den diabetesmedicin lægen har ordineret til dig?	Jeg får dosispakker fra apoteket

Wellbeing

WHO-5



RESPONSES

I felt cheerful and in good spirits	1	2	3	3	5	4	3
I have felt calm and relaxed	1	2	4	3	5	4	3
I have felt active and vigorous	1	2	4	4	5	5	1
I woke up feeling fresh and rested	1	2	3	4	5	4	2
My daily life has been filled with things that interest me	1	2	3	4	5	3	2
	20	40	68	72	100	80	44

1: All of the time
2: Most of the time
3: More than half of the time
4: Less than half of the time
5: Some of the time

Pittsburgh Sleep Quality Index (PSQI)

RESPONSES 20/06/01

During the past month, when have you usually gone to bed at night?	23:30
During the past month, how long (in minutes) has it usually take you to fall asleep each night?	30
During the past month, when have you usually gotten up in the morning?	6:30
During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spend in bed)	7
During the past month how often have you had trouble sleeping because you...	
Cannot get to sleep within 30 minutes	Not during the past month
Wake up in the middle of the night or early morning	Less than once a week
Have to get up to use the bathroom	Once or twice a week
Cannot breathe comfortably	Three or more times a week
Cough or snore loudly	Three or more times a week
Feel too cold	Not during the past month
Feel too hot	Less than once a week
Had bad dreams	Once or twice a week
Have pain	Three or more times a week
Other reason(s), please describe: Hear a beep in my ear	Three or more times a week
During the past month, how would you rate your sleep quality overall?	Fairly good
During the past month, how often have you taken medicine (prescribed or 'over the counter' to help you sleep?	Less than once a week
During the past month, how often have you had trouble staying awake while driving, eating meals or engaging in social activity?	Less than once a week
During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?	Not problem at all
Do you have a bed partner or roommate?	Partner in same bed
If you have a roommate or bed partner, ask him/her how often in the past moth you have had...	
Loud snoring	Not during the past month
Long pauses between breaths while asleep	Less than once a week
Legs twitching or jerking while you sleep	Once or twice a week
Episodes of disorientation or confusion during sleep	Three or more times a week
Other restlessness while you sleep; please describe	
Global PSQI Score:	C1: 2, C2: 0, C3: 0, C4: 1, C5: 0, C6: 2, C7: 1. Global: 6

Hospital Depression and Anxiety (HADS)

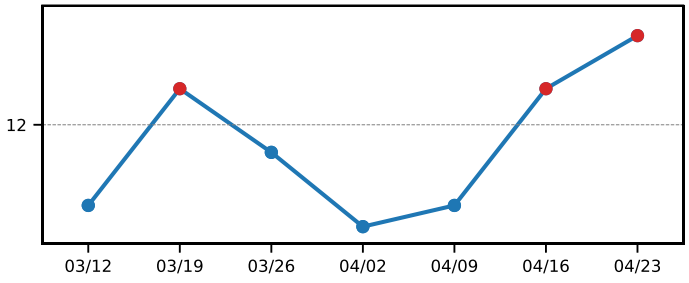
RESPONSES

	02/29	03/12	03/26	04/09	04/23	05/07	05/21
I feel tense or 'wound up':	1	3	3	2	2	1	1
I get a sort of frightened feeling as if something awful is about to happen:	1	1	3	2	1	1	1
Worrying thoughts go through my mind:	1	1	3	2	1	1	1
I can sit at ease and feel relaxed:	1	1	3	2	1	1	1
I get a sort of frightened feeling like 'butterflies' in the stomach:	1	1	1	1	1	1	1
I feel restless as I have to be on the move:	1	1	1	1	1	1	1
I get sudden feelings of panic:	1	1	1	1	1	1	3
Score Anxiety:	7	9	15	11	8	7	9
I still enjoy the things I used to enjoy:	1	1	1	1	1	1	1
I can laugh and see the funny side of things:	1	1	1	1	1	1	1
I feel cheerful:	1	1	1	1	1	1	1
I feel as if I am slowed down:	1	1	3	2	1	1	1
I have lost interest in my appearance:	1	1	3	2	1	1	1
I look forward with enjoyment to things:	1	1	3	2	2	3	1
I can enjoy a good book or radio or TV program:	1	3	3	2	3	3	1
Score Depression:	7	9	15	11	10	11	7

0: All of the time
1: Most of the time
2: Less than half of the time
3: Some of the time

Emotion and distress

Problem Areas in Diabetes (PAID)



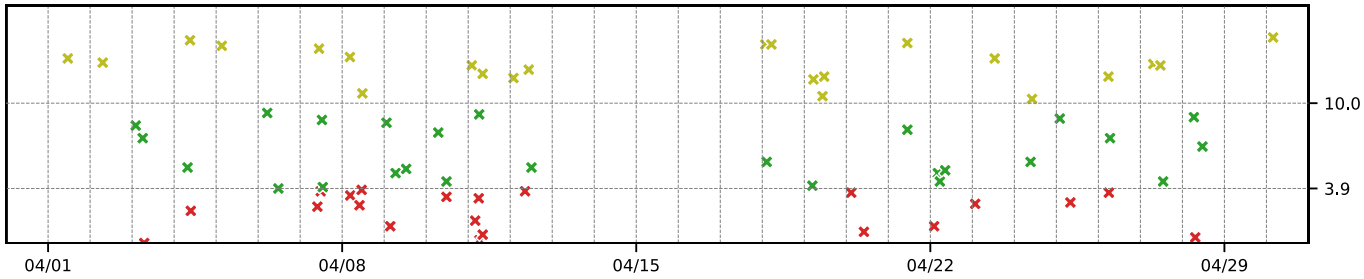
RESPONSES

Feeling depressed when you think about living with diabetes?	1	3	1	0	2	2	3
Feeling that diabetes is taking up too much of your mental and physical energy?	1	3	4	0	0	1	3
Feeling overwhelmed by your diabetes?		2	2			3	3
Feeling constantly concerned about food and eating?		2	0			3	3
Feeling alone with your diabetes?		2	0			2	3

Feeling “burned out” by the constant effort needed to manage diabetes?		1	0			2	3
PAID-6 combined score	2.5	16.25	8.75	0.0	2.5	16.25	22.5

0: Not a problem
1: Minor problem
2: Moderate problem
3: Somewhat serious problem
4: Serious problem

Blood glucose

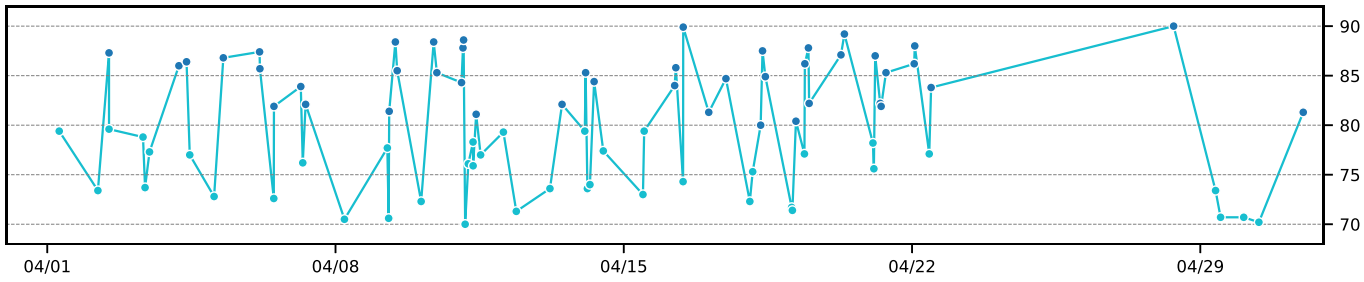


RESPONSES 14/02/20

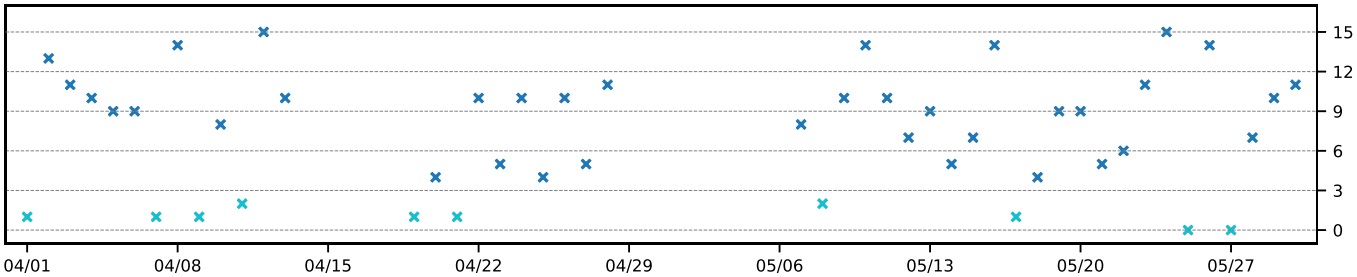
Do you use oral tablets to control your blood glucose?	Yes
Do you use insulin to control your blood glucose?	No
How often do you monitor your blood glucose levels at present?	3 times a day
In the past month, have you had any low blood glucose reactions? (Typical symptoms are sweating, heart pounding, difficulty concentrating, or irritability)	No
Did you need assistance from others during this low blood glucose reaction?	No

Lifestyle

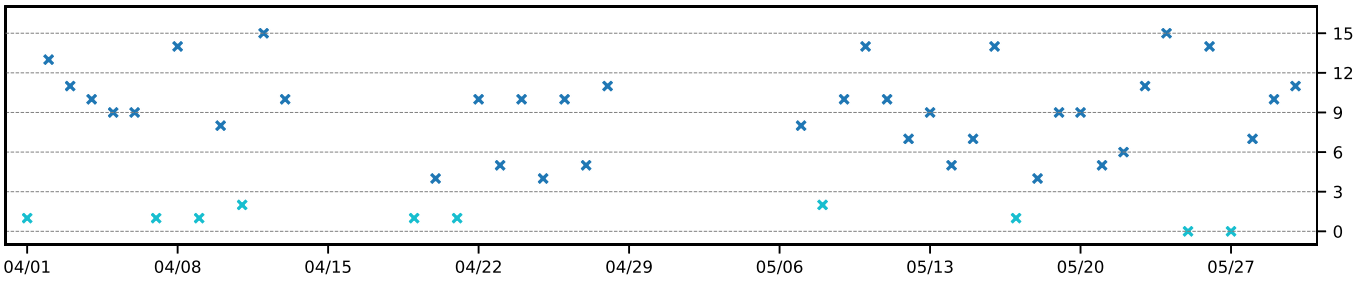
Weight



Alcohol

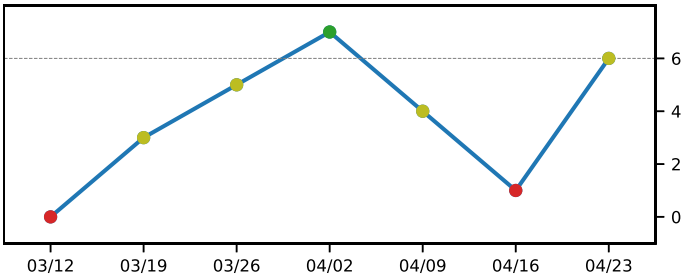


Smoking

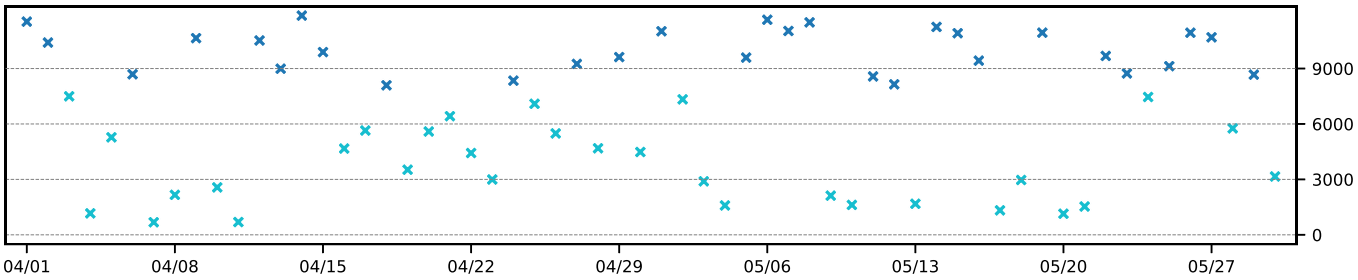


Exercise

How many days during the last week have you exercised for at least 30 minutes?



Steps



Diet

How many days during the last week have you followed a healthy diet (Sundhedsstyrelsens 10 kostråd)