Systematic Data Collection and Evaluation to Improve the Health Status of Diabetics

perfood

Starting Point

In early 2022, the nutritional medicine company Perfood was looking for a digital solution to investigate the impact of Glucura, a software-based program for accompanying lifestyle therapy for patients with type 2 diabetes mellitus. The program offers:

- a personalized analysis of the individual postprandial blood glucose response,
- guideline-based, digital support for dietary change,
- guidance on how to increase physical activity and
- knowledge lessons about the disease and appropriate lifestyle interventions.
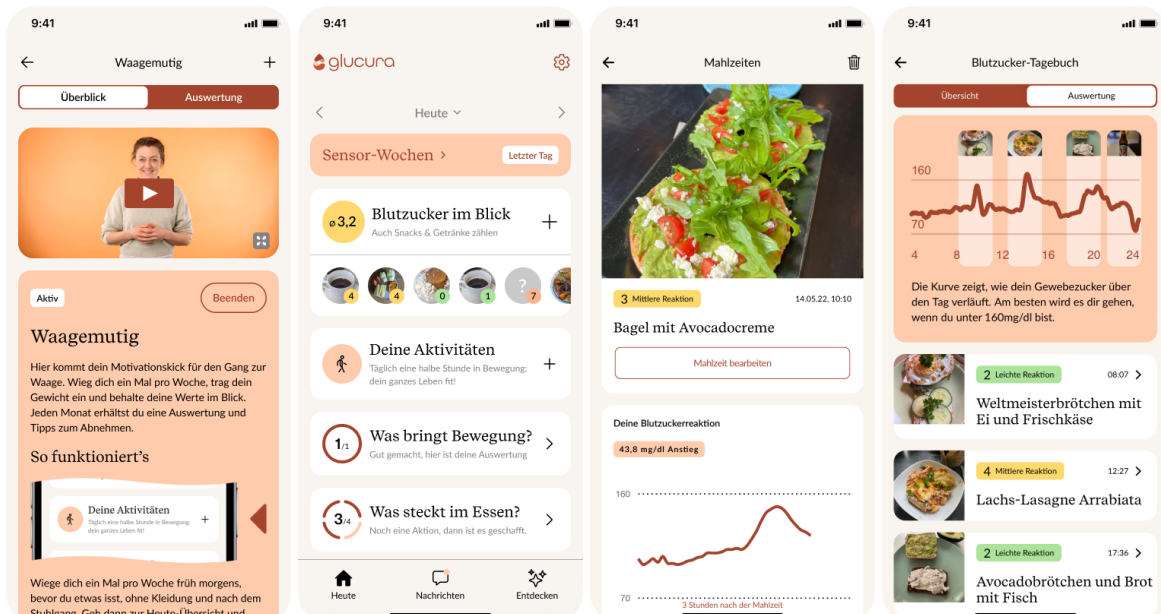

Figure 1: Insights into the software-based program Glucura. Source: Perfood (2022).

Personalized dietary recommendations can be derived through detailed analysis of continuously measured tissue glucose data collected via a glucose sensor. The additional individualized and structured challenges provide easy-to-follow guidance for dietary

changes and the integration of physical activity into daily life. This makes Glucura suitable for implementing the general lifestyle recommendations conveyed in the context of standard care.
The aim of the joint project with Climedo was to collect data on the experience of participants with the product and some additional parameters as part of the use of Glucura.

To ensure a successful data collection process, there was a need for a digital solution in which the surveys could be sent and the subsequent data viewed automatically. In the course of the survey, participants should receive four rounds of electronic questionnaires. It was also important for Perfood to be able to view the data in real time at all times.

Project Description

Perfood used a fully decentralized approach for the six-month data collection. Participation was possible from the comfort of one's own home. The target was 100 patients.

For the study, Perfood used the ePRO solution together with Climedo's eCRF module. At the beginning, Perfood received onboarding for the software. During a training session, Climedo's CSM team trained the managers at Perfood. The training video was also available afterwards. Perfood then set up the survey itself, configuring its own workflows including automatic reminders. The two companies were in close communication during this process. The survey went live within 2 weeks. This was followed by a review from Climedo to uncover hidden potential for improvement.

The data collection was divided into four different survey rounds. These were sent automatically to the participants at intervals of approximately three weeks. The aim was to find out what influence the use of Glucura has on the HbA1c value of the patients. In addition, participants received statements and questions to measure their adherence to the given program, such as:

- "I move as much (daily/weekly) and as often (activity per day/week) as recommended in the program."
- "I incorporate the exercise recommendations into my daily routine."
- "On average, on how many days a week did you use the app?"

If the questionnaires were not completed on time, the patients automatically received a reminder from Climedo.

Perfood also used Climedo's Benchmarking and Progression Widgets. The benchmarking widget allows for a defined data point of a subject to be anonymously compared with the benchmark of the overall study population. Here, Perfood looked in detail at the HbA1c value. Participants could be filtered by various demographic information, such as gender, age group, cohort, or region. The progression feature allows viewing the evolution of a defined data point of a subject collected over a period of time, such as several rounds of questions in this case. For data analysis and real-time insights, Perfood was able to access the Climedo Dashboard at any time.
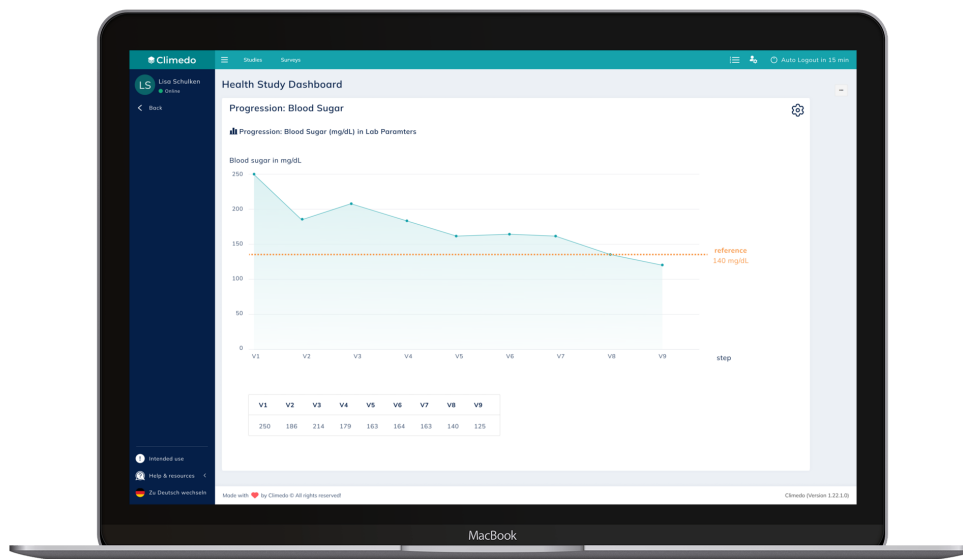
Figure 2: Evolution of the blood glucose level using the progression widget. Climedo-Software (2022).

Currently, the study is still ongoing.

Benefits and Results

In general, Perfood, like Climedo, also sees the advantages of electronic data capture, especially with regard to ePROs and eCRFs. Perfood had already gained experience with eCRFs before Climedo and was positively surprised by how quickly and easily the data entry screens could be created. The flexibility of the software was also an important criterion.

Compared to the outdated paper-based variant, Perfood also valued the advantage of plausibility checks and audit trails for transparent traceability.
The automatic reminder function for completing the ePROs was also found to be particularly practical. The software provided constant insight into the current data situation and the progress of the participants and survey – quickly at a glance. Using the visually appealing dashboard, the data quality could be checked live at any time. The dashboards also served as the basis for internal reporting. This enabled Perfood to keep a constant eye on the number of patients and their data.

For Perfood's Climedo users, being able to rapidly prepare data collection and create questionnaires was very advantageous as this saved a lot of time . Perfood perceived the operation of Climedo as intuitive and simple. Being able to create the questionnaires in a self-determined way was also perceived as positive. Perfood appreciated the fact that they were not dependent on much support and could act very autonomously, but at the same time a contact person was always available in case of queries.

Overall, Perfood particularly appreciated the ease of use, the quick set-up, the low costs, and the positive and productive exchange with the Climedo team during onboarding and implementation.

Conclusion and Perspective

Thanks to the ease of use of the software and the positive progress of the project, Perfood can imagine further follow-up projects with Climedo. Perfood would like to rely exclusively on one tool and combine information centrally in one place.

Customer Testimonials

"Climedo convinced us in particular with its intuitive operation and flexibility in implementing our data collection concept. We were able to set up and activate our project in a very short time. Perfood is primarily about the patient, so the ePRO/eCOA solutions offered were a convincing selling point when deciding on Climedo. The Climedo team is always friendly, always available and very helpful in solving problems."
- Dr. med. Dr. rer. nat. Torsten Schröder, Founder and Chief Medical Officer, Perfood GmbH

About Climedo

Climedo offers a digital health platform for hybrid clinical trials and observational studies. Its easy-to-use, modular and secure solutions for data management include electronic data capture (EDC), ePRO, eCOA, and Telemedicine. This enables pharma and medtech companies to validate their medical innovations more efficiently in the post-market phase and to capture data in decentralized, real-world settings. As a result, they accelerate studies, save costs, and improve data flow and quality, while fostering innovative trial designs. By connecting all stakeholders (industry partners, study sites, physicians and patients) in one cloud-based system, Climedo is revolutionizing clinical research and making trials more accessible and patient centric. Learn more at www.climedo.com.

About Perfood

Since 2017, Perfood has been combining modern science with digital technologies, making it one of the pioneers of the digital health age. Perfood GmbH was founded by Dominik Burziwoda (CEO), Dr. med. Dr. rer. nat. Torsten Schröder (Chief Medical Officer/ CMO), Dr. Christoph Twesten (CTO) and Prof. Dr. Christian Sina at the University of Lübeck, one of the leading German life science universities. The team consists of 50 experts from the fields of medicine, data science, nutrition, computer technology, business and design. Lead investors in Perfood include the Boehringer Ingelheim Venture Fund (BIVF), a leading investment company in the life science sector. In addition, the Lübeck-based company cooperates with leading research institutions such as the

Universities of Lübeck and Hohenheim, the Leibniz Association and the Helmholtz Association. The young company is growing strongly every year with three business areas: lifestyle (nutrition programs), digital therapies (including migraine prophylaxis) and research.