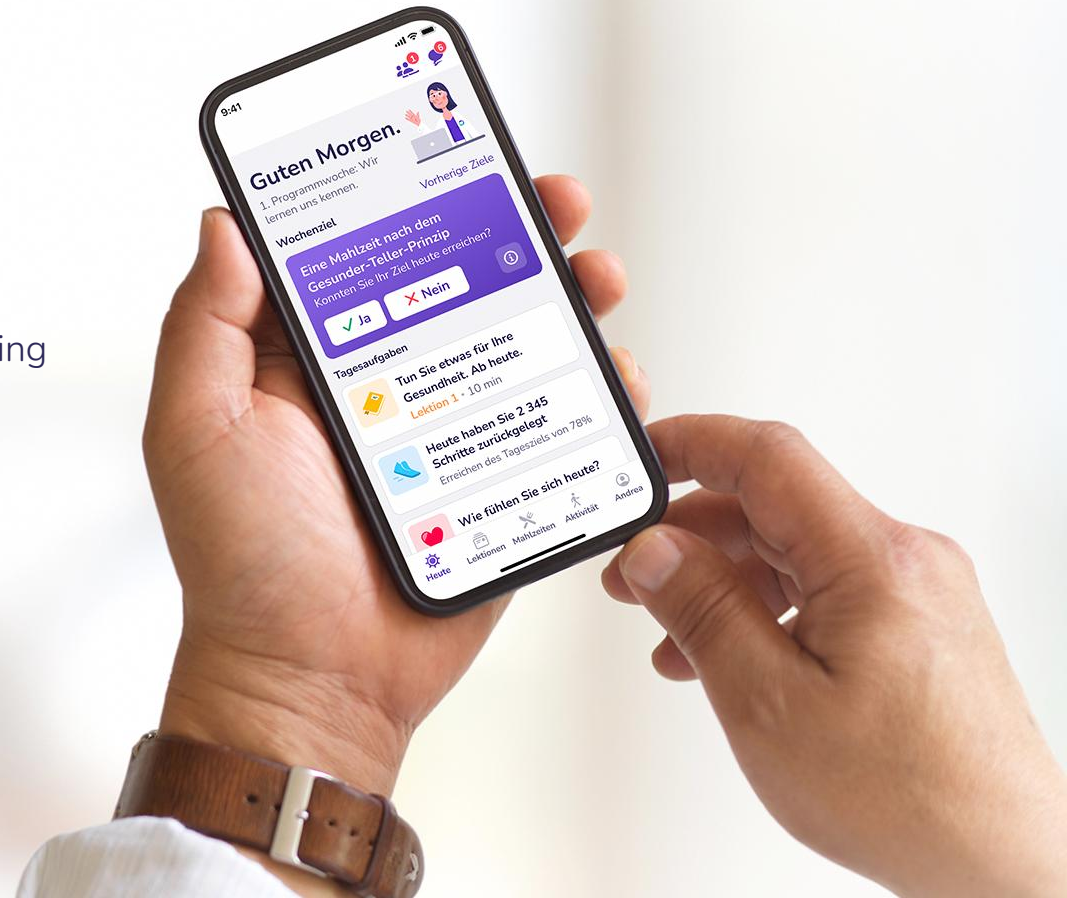# vitadio

Digital Therapeutics for Type 2 Diabetes

AI-driven lifestyle modification therapy reversing insulin resistance in type 2 diabetes patients.

Lenka Röhryová

December 2023

Vitadio is on a mission to **empower people with chronic conditions to restore their health** with digital technology.

vitadio

**2019** Started | **40** Team | **Prague/Berlin** Offices

Executive summary

- App on prescription complementing doctors' care
- The first universally reimbursed digital therapeutics for type 2 diabetes therapy (DiGA)
- Active on German, Czech and Italian market

Lifestyle Modification is Recognized as the First-line Treatment of Type 2 Diabetes with a Potential to Stop and Reverse the Disease
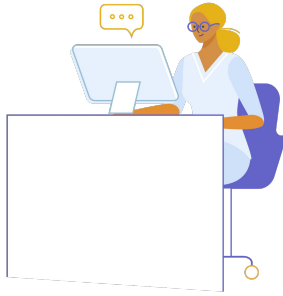
Less than 15% receive lifestyle therapy

- Only a fraction of patients receive support in changing lifestyle
- Patients feel lost between doctor's visits and often fail

Medication treats only symptoms

- Majority of patients are treated with medication only
- Without changed behaviour, the effect of medication is cancelled out

Diabetes progresses in 90%+ of cases

- Unchanged behaviour results in faster disease progression and treatment escalation

Vitadio is a **digital therapeutic** app supporting people with **type 2 diabetes** in restoring their **metabolic health**.

Our AI-driven multimodal lifestyle modification therapy is designed to sustainably improve diabetes control, reduce body weight and increase patients' quality of life.

CE — Class I medical device under MDR

GDPR compliant

Available for iOS and Android

Supported by clinical research

prescription DTX approved by BfArM

Certified data security (ISO 27001)

Certified quality management (ISO 13485)
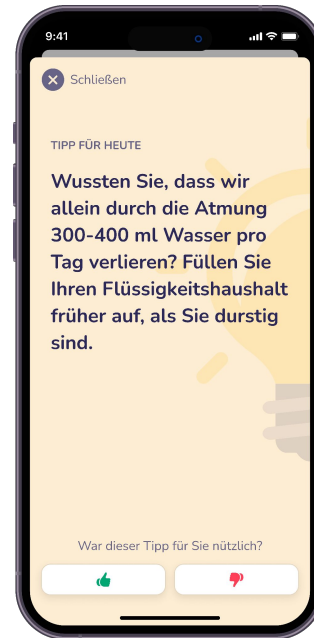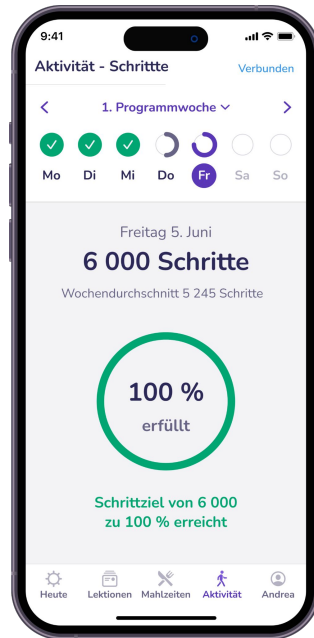
Therapy recommended by guidelines

Motivation to change

Health and behaviour tracking

Users track their health data, mood, diet and physical activity to become aware of their behaviour.

Practical daily tips

Users receive daily tips on how to make their life healthier and are supported by automated coaching messages based on their profile and behaviour.

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Ability to change

Instant meal feedback

The ALFRED algorithm provides feedback on meal photos in real time.
This allows users to learn about the nutrition in everyday situations at any time.

Interactive learning experience

Users learn about complex topics in an easy-to-understand way. This includes the topics of diabetes, nutrition, exercise, sleep hygiene, motivation and mental well-being.

ALFRED
Algorithmic Food Recognition Device

Creating the habits

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Adaptable to-do list

Patient are guided by a dynamic to-do list that develops with their progress. It nudges them to be consistent in their effort and motivates to make small steps every day.

Personalized goals

The users set themselves weekly goals to integrate new habits into their everyday lives. The achieavalbe goals support motivation to keep up.

Maintaining the change

Discussion group

Users can exchange encouragement, experiences and tips in an in-app discussion group and motivate each other.

Personal health coach

All users have a personal health coach available to ask questions via an initial phone call or chat.

Who are our users?
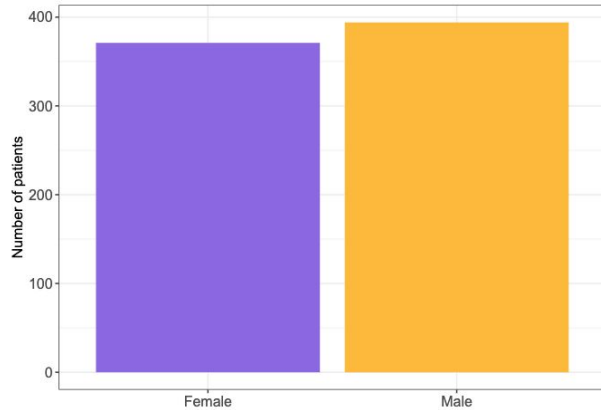
Equal share of men and woman
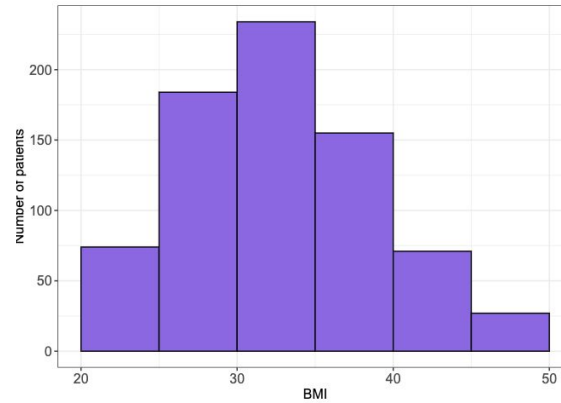
Average BMI: 33
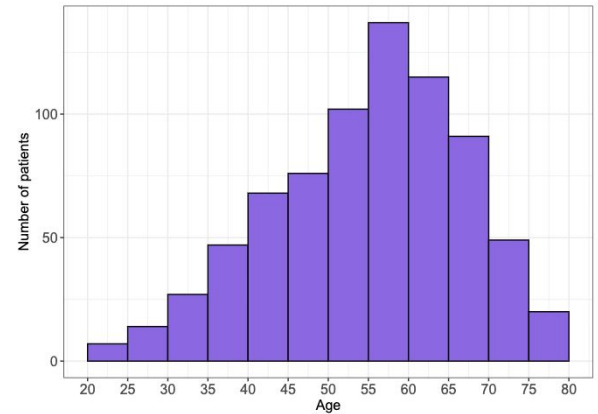
Average age: 56 years

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How do patients use the app? (n=823)

100 min — users spends monthly in the app

14 — users interact with the app 14 times a day

80% — of users track their weight and mood regularly

70% — of users read all educational materials

Source: Vitadio 2023

Vitadio Matches Intensive Face-to-Face Care

- Vitadio group reduced body weight by **-5.5 ± 4.8%** after 3 months and maintained it
- Vitadio group achieved a superior change in body composition and reducing insulin resistance
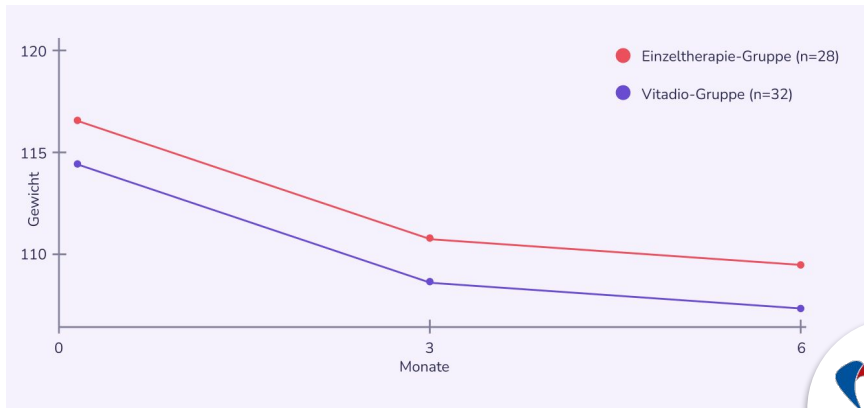
Participants
- n= 100 (30% men, average age 43 years, BMI: 40 kg/m2)
- 84 and 60 participants completed the 3- and 6-month follow-up respectively

Comparator
- 5 individual consultations
- Online diary tool
- Remote contact person:in as required

Nominiert für den **Nutrients 2024 Best Paper Award**

Improvement in Diabetes Control **Comparable to Drugs**

With Vitadio, **2.6x more patients achieved** recommended level of HbA1c compared to standard of care. The reduction of HbA1c is **comparable to oral antidiabetic agents**.
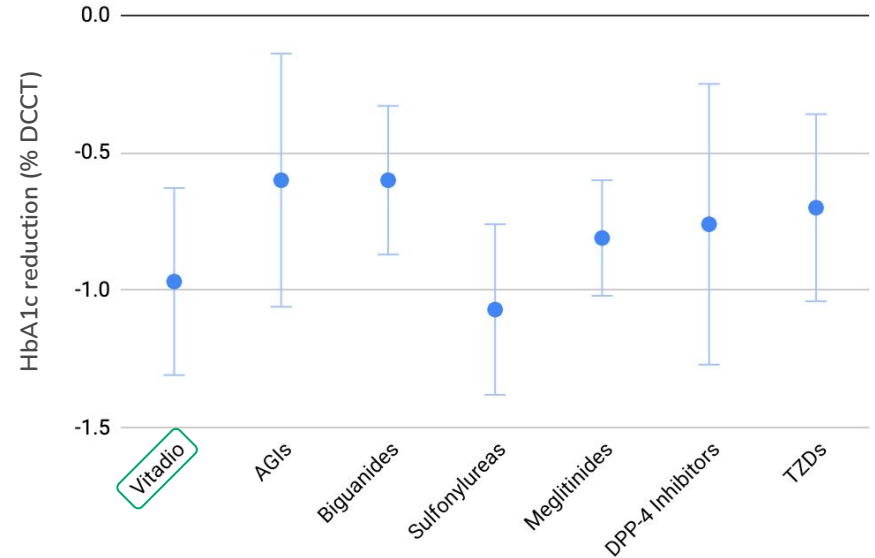
3-month HbA1c change with 95 % CI (Vitadio vs. antidiabetic agents)*

HbA1c (%) (n=40 each)	Baseline values	3-month follow-up	Change	p-value
Vitadio	7.9±1.0%	6.9±0.9%	**-0.9±1.1%**	<0.001
Control	8.2±1.3%	7.9±1.0%	-0.3±1.1%	0.32

*Sherifali, D., Nerenberg, K., Pullenayegum, E., Cheng, J. E., & Gerstein, H. C. (2010). The effect of oral antidiabetic agents on A1c levels: a systematic review and meta-analysis. *Diabetes care*, *33*(8), 1859–19.

How can patients get Vitadio?

Digitale-Versorgung-Gesetz from November 2019 (Digital Healthcare Act)
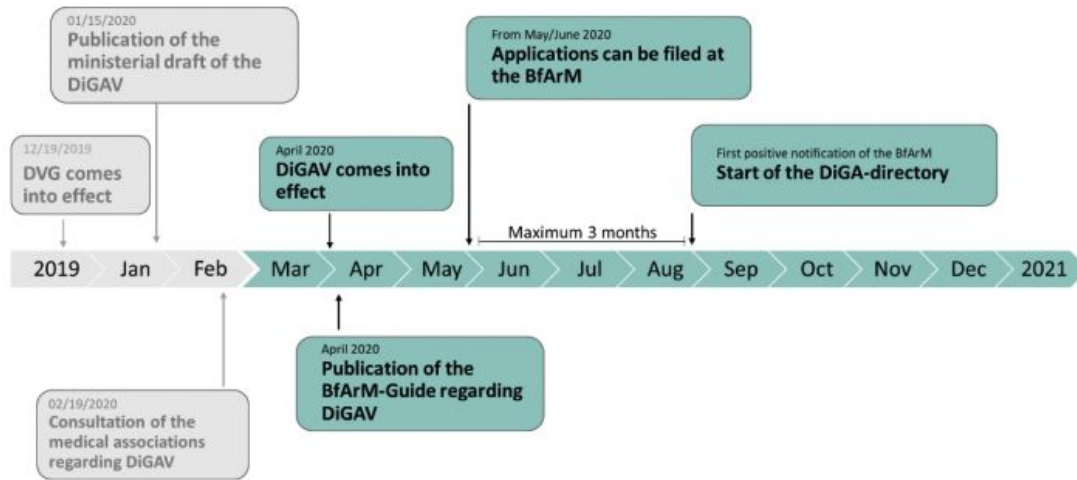
Figure 2: Implementation of the Fast Track procedure.
Source: BfArM.

Prescription process in Germany

Option 1: Prescription

Patient seeks medical treatment

Physician prescribes a DiGA as part of a therapy

Prescription of a DiGA on a **prescription form #16**

Option 2: Request/Release

Based on a medical indication, the **Patient** searches for a DiGA.

Search for information regarding **specific DiGAs**

Patient sends a **request for usage** to his health insurance company

Based on the **redeemed prescription code**, invoicing to the health insurance company can be created as soon as the contractually agreed remuneration parameters are reached.

DiGA-Manufacturer

The DiGA manufacturer **provides access** to his DiGA in an App Store or on the homepage. As soon as a patient downloads and activates a DiGA, the **prescription code is transmitted.**

health insurance company

DiGA plattform

The health insurance company verifies the prescription or the patient's request and **sends a prescription code.**

Patient

The **prescription code** enables the patient to download the DiGA from the corresponding platform and **activate** it without charge.

schönermark kielhorn collegen *Prescription and invoicing cycle of digital health applications*
Source: SKC according to Health Innovation Hub

![vitadio logo]

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How long does it take an average manufacturer to get through the process?

20% success rate

Price is reduced after the price negotiation to 190-240 EUR per quarter

Development & CE	Pre-Study	Fast Track Preliminary	Approval	Observation Study	Fast Track Permanent	Approval	Preisverhandlung
12 months	6 months	4 months		12 months	4 months		

Time until Preliminary Listing → 22 months

Time until Permanent Listing → 38 months

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BfArM admission procedure
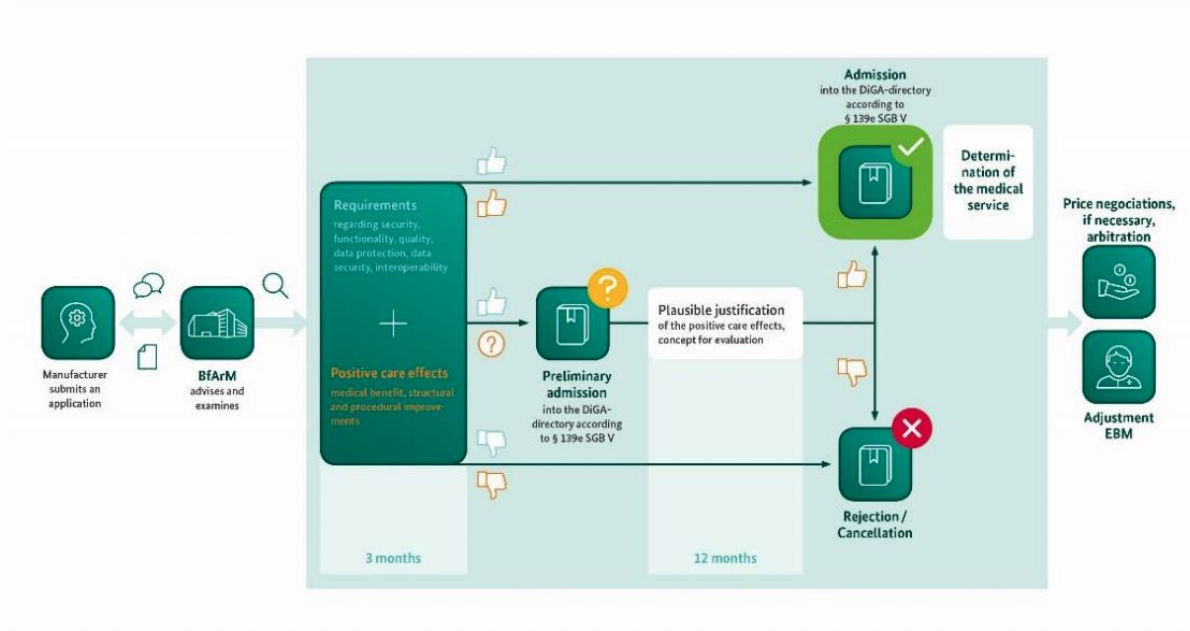
Figure 1: Sequence of the Fast Track procedure.
Source: BfArM.

How much does it cost?
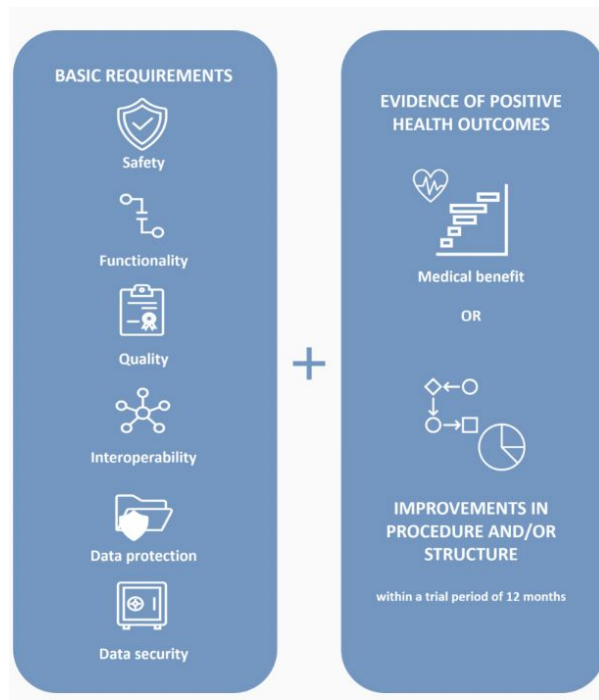
DiGA Pre-Study:	~ 200 – 400k
CE-Marking process (Class I)	~ 100 – 200k
Other Certificates and technical requirements:	~ 200 – 300k
Consulting (study, process, product requirements, preparations etc.):	~ 200 – 300k
2-3 FTEs internal working on DiGA:	~ 200 – 300k
Legal Support	~ 50 – 100k
Total	~ 950k – 1.6m

About DiGA

Digitale Gesundheitsanwendung (Digital Health Application)

- ☑ Medical device
- ☑ Conformity procedure according to MDR
- ☑ Risk class I or IIa
- ☑ Main function based on digital technology
- ☑ Does not serve the purpose primary prevention
- ☑ In the hands of the patient

200 Basic Requirements + Evidence of positive health outcomes

BASIC REQUIREMENTS

Safety

Functionality

Quality

Interoperability

Data protection

Data security

+

EVIDENCE OF POSITIVE HEALTH OUTCOMES

Medical benefit

OR

IMPROVEMENTS IN PROCEDURE AND/OR STRUCTURE

within a trial period of 12 months

Evaluation study

Study design must be approved by BfArM

Medical Benefits	• Improvement of state of health • Reduction of disease duration • Prolongation of survival • Improvement in quality of life • ...

AND/OR

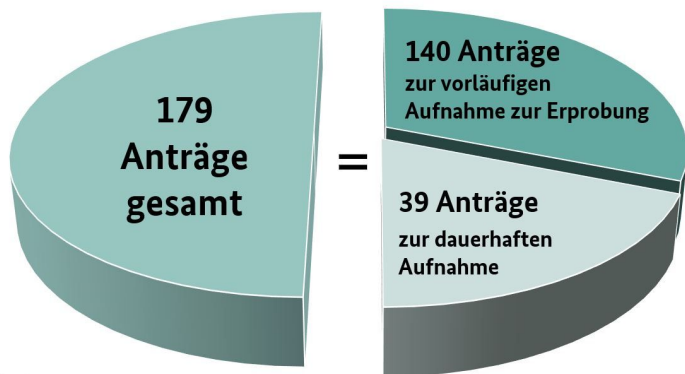| Patient-relevant improvement of structures and processes	• Coordination of treatment procedures • Alignment of treatment with guidelines and recognized standards • Adherence • Facilitated access to care • Patient safety • Health literacy • Patient autonomy • Coping with illness-related difficulties in everyday life • Reduction of treatment-related effort and burden for patients and their relatives • ...

Trial phase extension
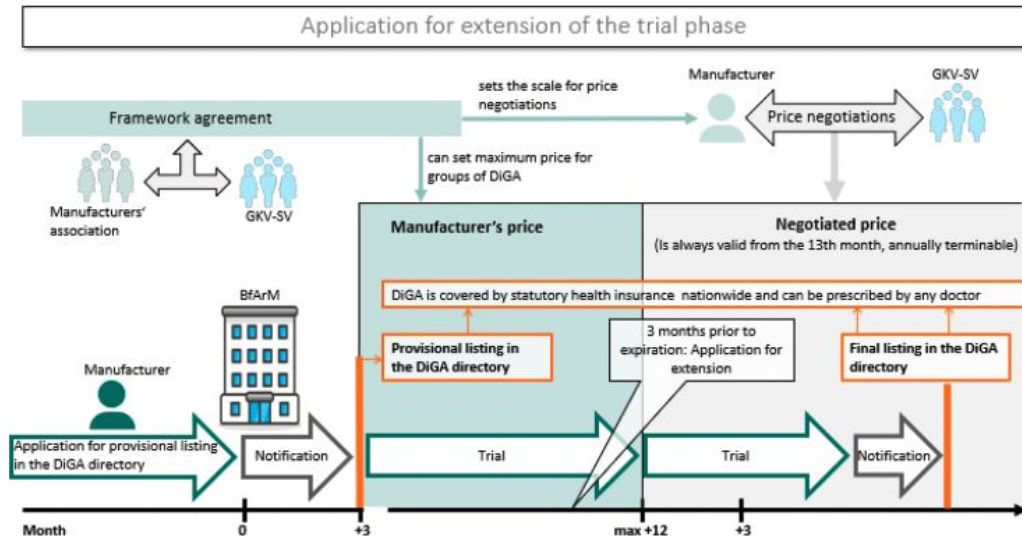
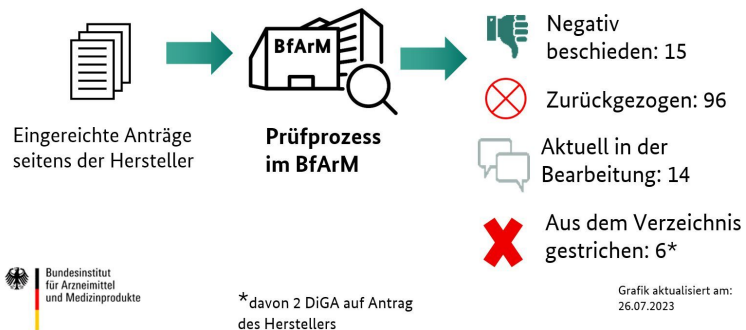Figure 5: Application for an extension of the trial phase.
Source: BfArM.

Success rate

Wie viele Anträge wurden seit dem Start des
DiGA-Antragsportals zur Prüfung beim BfArM eingereicht?

179 Anträge gesamt

=

140 Anträge zur vorläufigen Aufnahme zur Erprobung

39 Anträge zur dauerhaften Aufnahme

Bundesinstitut
für Arzneimittel
und Medizinprodukte

Grafik aktualisiert am:
26.07.2023

Was ist das Ergebnis zu den bisherigen
Prüfungen der Anträge im BfArM?

Eingereichte Anträge
seitens der Hersteller

Prüfprozess
im BfArM

Im Verzeichnis gelistet: 48

Negativ beschieden: 15

Zurückgezogen: 96

Aktuell in der Bearbeitung: 14

Aus dem Verzeichnis gestrichen: 6*

Bundesinstitut
für Arzneimittel
und Medizinprodukte

*davon 2 DiGA auf Antrag
des Herstellers

Grafik aktualisiert am:
26.07.2023

Non-inferiority Randomized Controlled Trial:
Vitadio Matches Intensive Face-to-Face Care in Diabetes Prevention

Vitadio achieved **equivalent or superior outcomes** compared to high-intensity care with 5 face-to-face sessions at 3 months

3- month change	Weight kg	Fat* %	Muscels %	HOMA*
Vitado	-6.6 ± 6.3**	-6,4± 5.0**	0,2± 2.1	-2,5± 5.2**
Face to Face	-4,8±5.7**	-4,2± 4.2**	-0,3± 1.4	+0,7± 5.4

*p < 0.05; ** p < 0.01, All data are presented as mean ± SD, fat and HOMA index are significantly different between groups
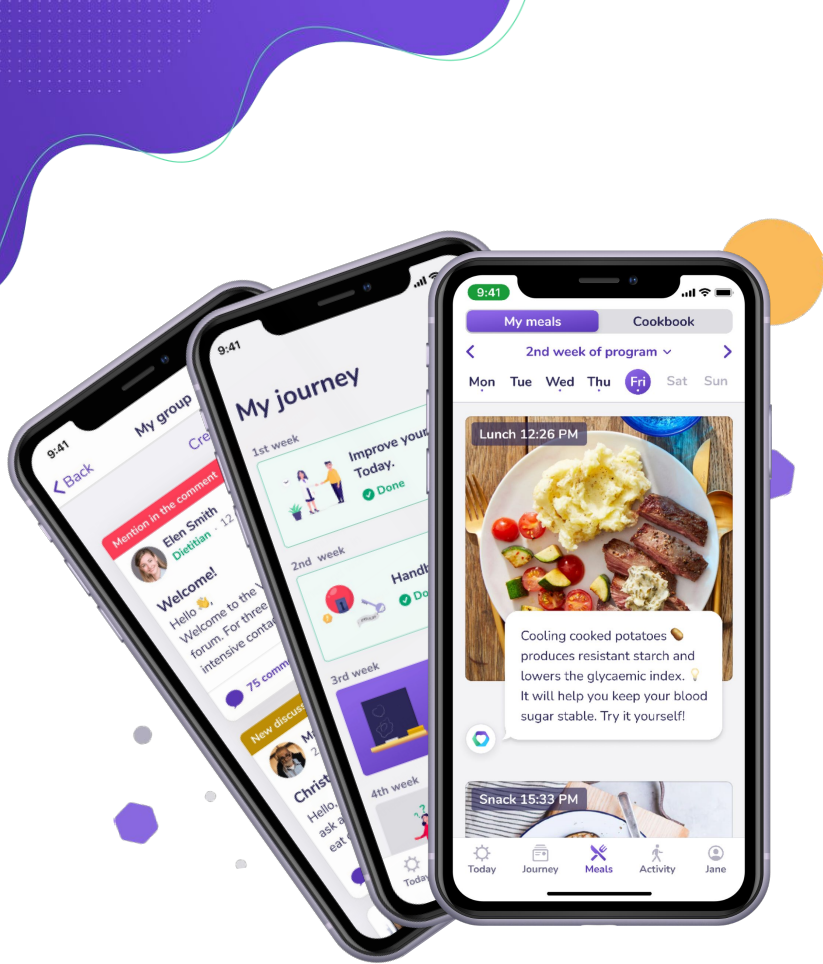
Unexpected attrition pattern: Vitadio dropouts achieved better results at 3 months than CG dropouts (**IG: -8.7 kg vs CG: -1.8 kg**)

6- month change	Weight kg	Fat %	Muscels %	HOMA
Vitado	− 7.3 ± 6.8**	− 7 ± 6.8**	0.0 ± 2.4	− 2.5 ± 5.2*
Face to Face	− 8.3 ± 8.2**	− 7.7 ± 6.7**	− 0.3 ± 1.5	− 1.0 ± 2.3

24 subjects (IG:10; CG:14) dropped out between the 3- and 6-month visit

UNIVERSITY HOSPITAL OLOMOUC

nutrients

Nominated for **Nutrients 2024 Best Paper Award**

Moravcová, K.; Karbanová, M.; Bretschneider, M.P.; Sovová, M.; Ožana, J.; Sovová, E. Comparing Digital Therapeutic Intervention with an Intensive Obesity Management Program: Randomized Controlled Trial. Nutrients 2022, 14, 1810. https://doi.org/10.3390/nu14102005

Comprehensive diabetes education

- 6-month personalized course covers self-management, diet, exercise, sleep and mental wellbeing
- Interactive learning with self-experiments and daily tips

Smart nudging

- Personalized goals to integrate habits into daily life
- Targeted messages based on readiness to change and progress

Proactive human support

- In-house certified health coaches on chat and phone
- Peer support group for users

Access to certified health coaches

- Distributed team of registered dietitians on chat and call
- Our proprietary dashboard evaluates patient progress and helps proactively address at-risk patients
- Quality management, training and knowledge sharing

Peer support group

- In-app social network for patients
- Sharing experience, motivation and achievements
- Moderated by health coaches
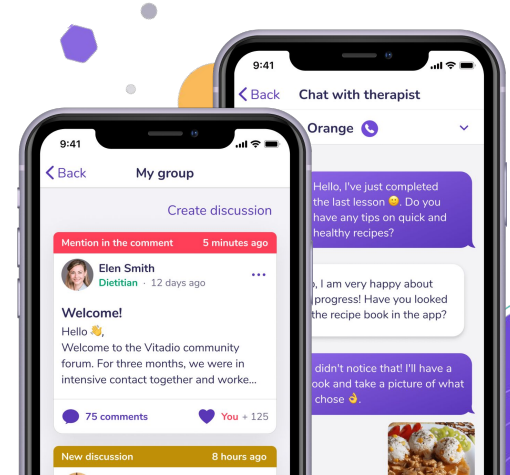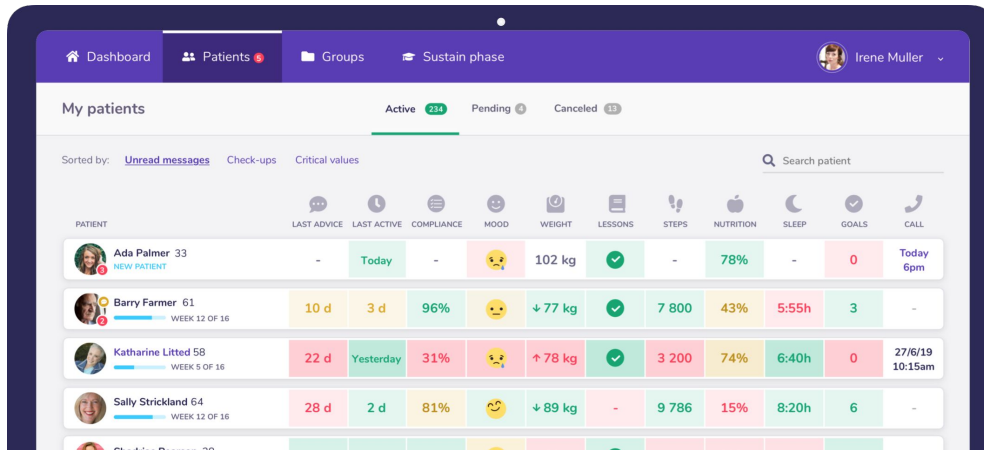
ALFRED

Algorithmic Food Recognition Device

AI-driven meal photo feedback

Our proprietary AI model provides real-time diet feedback and recommendations. Just like a human dietitian but anywhere and at the time the user needs it.

Personalized nudges

Users receive automated coaching messages based on their readiness to change and behaviour.