Digital IBS Therapy: Cara Care publishes promising study results on the effectiveness of the world's only multimodal app therapy for irritable bowel syndrome (IBS)

Hamburg, 17 October 2023 - The results of a randomised controlled trial for the digital health app (DiGA) Cara Care for IBS have now been presented, in which more than two thirds of the patients who used Cara Care over 12 weeks recorded a clinically relevant improvement in symptoms. Cara Care for IBS is a product of HiDoc Technologies GmbH, based in Hamburg and represented by CEO James Mapes and founder Dr André Sommer. The head of the clinical trial was Prof. Dr. med S. Lüth, Clinic Director Centre for Internal Medicine at the University Hospital Brandenburg an der Havel. According to Prof Lüth, "[d]igital therapies [...] represent a completely new treatment option and I am very pleased to be involved in this pioneering study. Evidence generation at the highest level is important to build confidence in such modern approaches. The results of the study speak for themselves and underpin the possibilities of digital medicine."

The study was conducted to provide evidence of the efficacy of the digital IBS therapy and thus enable permanent inclusion in the DiGA directory. James Mapes, CEO of Cara Care, describes the study results as follows: "The clearly positive results of the study carried out not only prove the effectiveness of our app, but are thus another milestone on the way to a better quality of life for those affected".

- Cara Care for IBS is the first and so far only approved digital health app (DiGA) for the treatment of irritable bowel syndrome (IBS), developed and published by the digital health start-up HiDoc Technologies GmbH.
- IBS is a widespread chronic disease that severely limits the quality of life of those affected. It is estimated that around 11 million people in Germany are affected (BARMER Doctor’s Report 2019[1]).
- The study demonstrated significant effectiveness of the DiGA in the areas of symptom severity, quality of life, work productivity and activity limitations, and health literacy.

Severe restriction of quality of life for IBS sufferers
Irritable bowel syndrome (IBS) is a common functional gastrointestinal disorder for which no identifiable organic cause can be found. The diagnosis is made after a specific examination to rule out other possible diseases. The estimated 11 million people in Germany who suffer from it may experience cramping abdominal pain, constipation and/or diarrhea, a feeling of pressure and fullness after eating, and flatulence repeatedly over a long period of time, which often leads to a considerable impairment of their quality of life. Treatment of IBS involves various approaches, including medical education, drug therapy to alleviate symptoms if necessary, nutritional counselling and, in some cases, psychotherapy (S3 guidelines for IBS)[2]. Cara Care for IBS is the world's only digital IBS therapy that combines

[1] BARMER Doctor's Report 2019. Series of publications on health analysis [German article]. Grobe, Steinmann, Szecsenyi. Volume 14
[2] Layer P, Andresen H, Allescher H, et al.: S3 guideline update on irritable bowel syndrome: Definition, pathophysiology, diagnosis and treatment. Joint guidelines of the German Society for Gastroenterology, Digestive and Metabolic Diseases (DGVS) and the German Society for

both the nutritional therapy aspect and psychotherapeutic modules. According to the guidelines, the digital health app (DiGA) offers a personalised therapy option that combines several areas in one solution. These include the low-FODMAP diet, cognitive behavioural therapy and gut-directed hypnosis. Prof. Dr. med. Martin Storr, gastroenterologist, irritable bowel specialist and co-author of the currently valid medical guideline on irritable bowel syndrome has supported HiDoc Technologies GmbH in the conceptualisation of bowel hypnosis in the DiGA: "I very much welcome the fact that guideline-compliant procedures, such as bowel-directed hypnosis, can now also be made accessible via a DiGA. The new study data show that the approach of digital irritable bowel therapy is feasible."

Design of the study

A total of 378 patients were included in the randomised controlled trial. Randomly, 188 patients were divided into an intervention group and 190 patients into a control group. The intervention group received direct access to the DiGA Cara Care for IBS, while the control group received access to an app consisting only of DiGA questionnaires. At the end of the 12-week therapy period, the control group also received access to the DiGA and the 12-week therapy programme. Since irritable bowel syndrome is a disease that can be accompanied by phases of varying symptom severity (S3 guideline for irritable bowel syndrome[3]), the control group serves to take this natural course of the disease into account. In the study, the patients answered various questionnaires that are standardly used in research to measure symptom severity, quality of life, limitations in terms of work productivity and daily activities, as well as health literacy. For the evaluation of the study data, the development of these measures before and after treatment was compared between the intervention and control groups.

Results of the study

Patients in the intervention group using the DiGA Cara Care for IBS showed much greater improvements in symptom severity, quality of life, impaired work productivity, impaired activity and health literacy after the 12 weeks than the control group. For the control group, there was mostly little to no improvement. The difference between the two groups was significant ($p<.0001$) for all endpoints assessed. "We are proud of this clearly positive outcome of the study and look forward to continuing to establish Cara Care for IBS in the treatment of IBS", comments Dr André Sommer, co-founder of Cara Care.

66.5% of the patients in the intervention group (125/188) experienced a clinically relevant improvement in symptoms. In the control group, this was only 33.2%. This means that 3 patients would have to be treated with Cara Care for IBS in order to achieve a clinically relevant symptom reduction in at least one patient. By comparison, a drug therapy for IBS with antispasmodics would have to treat six patients to achieve similar effects (Quartero et al. 2005[4]). The results of the study thus speak for a high effectiveness of Cara Care for IBS.

Neurogastroenterology and Motility (DGNM) - June 2021 - AWMF registration number: 021/016. Z Gastroenterol 2021; 59 (12): 1323-415.

[3] Layer P, Andresen H, Allescher H, et al.: S3 guideline update on irritable bowel syndrome: Definition, pathophysiology, diagnosis and treatment. Joint guidelines of the German Society for Gastroenterology, Digestive and Metabolic Diseases (DGVS) and the German Society for Neurogastroenterology and Motility (DGNM) - June 2021 - AWMF registration number: 021/016. Z Gastroenterol 2021; 59 (12): 1323-415.

[4] Quartero AO, Meineche-Schmidt V, Muris J, Rubin G, de Wit N. Bulking agents, antispasmodic and antidepressant medication for the treatment of irritable bowel syndrome. Cochrane Database Syst

The study data were presented for the first time in the form of an abstract at the UEG Week in Copenhagen, an international congress where high-ranking research results from the leading minds in the field of gastroenterology are presented to a professional audience. The abstract can be found at this link.

Contact:
Fiona Walter
PR Manager
press@cara.care

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