A Prospective Pilot Study of the Allurion Digital Behaviour Change Intervention

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To determine DBCI acceptability by examining how participants respond to the intervention, their views, perceptions, thoughts, feelings, benefits and barriers. To determine DBCI acceptability by examining Elipse providers views, perceptions,...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49911

Source
ToetsingOnline

Brief title
DBCI

Condition

- Other condition
- Eating disorders and disturbances

Synonym
Obesity, overweight

Health condition

obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Allurion Technologies
Source(s) of monetary or material Support: Vanuit het bedrijf Allurion Technologies

Intervention

Keyword: Behavioural change, Gastric balloon, Lifestyle intervention

Outcome measures

Primary outcome

The primary outcome measure for this intervention is the change in % total body weight loss (%TBWL).

Secondary outcome

Change in psychological outcomes*known to influence successful weight loss and maintenance including mood, anxiety, Health-related Quality of Life (QoL) and overall wellbeing; self-efficacy and ability to self-regulate emotions, thoughts and behaviours relating to weight management.

Changes in BMI, body composition, time spent in physical activity (aerobic exercise and steps), sleep, heart rate and dietary intake (calories and macronutrients).

Acceptability, barriers and facilitators to implementing the DBCI from a participant and provider perspective.

Participant engagement with DBCI and provider after-care support.

Study description

Background summary

Obesity and Intragastric Balloon Treatment
Obesity is a chronic, debilitating, multi-factorial disease that has reached worldwide pandemic proportions1. The prevalence of obesity has tripled since the 1980s in many countries of the World Health Organization (WHO) European region. In addition, the prevalence of overweight and obese people in the United Kingdom (UK) continues to increase at an alarming rate and is a trend that will be difficult to reverse. The WHO estimates that by 2015, 2.3 billion people will be overweight and over 700 million will be obese. Furthermore, the movement of people into the obese category (Body Mass Index (BMI) > 30) continues to increase by 1% of the population per year2, and within this group the percentage of people moving into the Class III, or morbid obese group, has almost doubled over the last ten years with an estimated prevalence of 2.2%3.

Significant evidence indicates that successful treatment of obesity results in a reduced incidence of co-morbid diseases. Specifically, a 5-10% total weight loss can significantly reduce or prevent coronary heart disease, hyperlipidemia, hypertension, type 2 diabetes, and other chronic diseases in obese individuals4-8. A combination of calorie restricted diet, regular physical activity, and behavioral modification with or without pharmacotherapy has been utilised to treat obesity; however, a significant weight loss of 10 to 15% is rarely achieved or sustained9. For morbid obesity, bariatric surgery is the only treatment option with sustainable weight loss10. However, some patients with moderately increased BMI do not qualify for bariatric surgery or prefer less invasive treatment modalities. In these patients, an intragastric balloon (IGB) can help them adhere to lifestyle modification, preventing the need for bariatric surgery. IGB treatment, in addition to lifestyle modification, has been shown to be an effective short-term modality for weight loss11.

The Elipse Gastric Balloon System, manufactured by Allurion Technologies, is designed to not require endoscopic placement or removal. The balloon is swallowed by the patient in the ambulatory setting without sedation, anaesthesia or endoscopy. It is designed to reside in the stomach for approximately 16 weeks, after which its degradable release valve opens enabling the device to empty. The empty balloon transits the GI tract and is naturally excreted. Since receiving European regulatory approval in 2015, more than 39,114 Allurion gastric balloons have been distributed and deployed in patients in 38 countries through December 2020. Data from 1,770 consecutive Allurion Gastric Balloon System patients (F 1264/M 506) treated in 19 centers across 7 countries in Europe and the Middle East were collected to evaluate weight loss, metabolic parameters, and device performance. The mean baseline age was 38.8

years, mean baseline weight of 94.6 kg, and mean BMI was 34.4 kg/m2. After 4 months, overall mean weight loss was 13.5 ± 5.8 kg and mean BMI reduction was 4.9 ± 2.0 points. Percentage total body weight loss was 14.2 ± 5.0%. All metabolic parameters (including LDL, HDL, and HbA1c) improved12.

Development of a Digital Behavioural Component for Improved Outcomes

Despite the Elipse Gastric Balloon System showing significant short-term post-operative weight loss trajectories for many patients, these findings are not universal primarily due to lack of adherence to lifestyle modifications. To achieve maximum weight loss and prevent weight regain, it is recommended that patients increase physical activity, decrease sedentary behaviours, and adhere to dietary recommendations. Unfortunately, these patients often face numerous challenges (e.g., transportation, geographical, time) that prevent them from seeking further assistance or support to improve and prolong weight loss outcomes. Current studies document the promising effects of use of mobile and online technologies (eHealth), including wearable devices for improving health outcomes among those with obesity by eliminating transportation, geographical and time barriers13. Post-IGB weight loss and weight loss maintenance interventions that are accessible, cost-effective and scalable are not only desirable, but have the potential to improve and sustain health outcomes14.

The United States Preventive Services Task Force (USPSTF) and the Obesity Society found adequate evidence that intensive, multicomponent*behavioural*interventions in adults with obesity can lead to clinically significant improvements in weight status. The USPSTF also found adequate evidence that the harms of intensive, multicomponent behavioural interventions (including weight loss maintenance interventions) in adults with obesity are small to none. Therefore, the USPSTF concludes with moderate certainty that offering or referring adults with obesity to intensive*behavioural*interventions or*behaviour-based weight loss maintenance interventions*has*a moderate net benefit15,16.*

The increasing prevalence and disease burden of obesity necessitate the development of novel methods to support weight management17. Digital behaviour change interventions (DBCI) have the potential to provide a tailored, accessible, scalable and cost-effective solution for people with overweight and obesity, with benefits extending to non-weight outcomes such as the reduction of depression risk and depressive symptoms18. Current studies show that the delivery of obesity treatment eHealth strategies is both cost effective and scalable19,20. Many eHealth systems are used to set and track individual goals, to monitor diet and physical activity and to create tailored responses based on behaviour change progress. Specifically, in a meta-analysis of eHealth weight

loss or weight maintenance interventions Hutchesson et al. reported modest weight loss compared with no behaviour treatment or minimal treatment. eHealth interventions with features including self-monitoring and personalized feedback or technologies such as text messages and social media were more effective than standard eHealth programs21.

There is increasing evidence to support the use of DBCI in adults with obesity and type 2 diabetes. Given that type 2 diabetes is one of the most prevalent co-morbidities associated with severe obesity, it is logical to think that these same strategies may be effective in pre- and post-IGB education, knowledge, behaviour change and social support delivery. However, it is also important to measure the acceptability of such strategies, and whether they improve IGB outcomes. Das et al. reported that an eHealth portal tailored to provide postoperative metabolic and bariatric surgery support decreased attrition rates in clinical follow-ups and improved patients* health22. Additionally, the portal became a safe outlet where patients could express their concerns and seek assistance in real-time. It also allowed providers to better tailor their care to meet the patients* needs.

No studies to date have specifically reported outcomes or effect sizes for DBCIs targeting IGB patients. As such, there is an opportunity to develop engaging and effective DBCI strategies and products targeting IGB patients.

Development of the Allurion Digital Behaviour Change Intervention

The Allurion DBCI adheres to current National Institute for Health and Care Excellence (NICE) guidance for obesity23. This is illustrated by the following:

It is a multicomponent intervention, which is *treatment of choice* for obesity.

It includes evidence-based behaviour change strategies to increase physical activity/reduce inactivity, improve eating behaviour, quality of diet and reduce dietary intake.

It is individualised for the person*s needs and circumstances.

It provides personalised and responsive support.

NICE guidance for obesity behavioural interventions also recommends inclusion of the following strategies, some of which are commonly known in the behavioural science literature as *Behaviour Change Techniques* (BCT):

Self-monitoring of behaviour and progress.

Stimulus control.

Goal setting.

Ensuring social support.

Problem solving/strategies for dealing with weight regain.

Cognitive restructuring.

Reinforcement of change.

Relapse prevention.

These strategies are implemented in the Allurion DBCI. Participants in this study will be guided through a personalised DBCI, designed to improve dietary, physical activity, sleep, self-regulation, mood and stress-related behaviours. The program promotes participant autonomy and includes ongoing and iterative feedback loops of self-monitoring, feedback, goal setting and action planning strategies, behavioural control/regulation and revision of goals and action plans.*

Behaviour modification in general and comprehensive lifestyle interventions that incorporate evidence-based BCTs are currently the cornerstone of obesity management. As might be expected, the key target outcomes for the Allurion DBCI are changes in diet and physical activity. In order to achieve these outcomes, it is necessary to identify the many target behaviours associated with success in relation to these outcomes. In order to do this systematically, a well recognised behavioural science framework - The Behaviour Change Wheel (BCW) was used24.

The first stage sought to identify key target behaviours associated with the outcomes, and then to understand the various barriers and facilitators that individuals face in achieving these target behaviours. This included a rapid review of the literature and review of qualitative and quantitative data collection from previous Elipse Gastric Balloon System patients. An exploratory mapping of the behavioural insights collected from this was achieved using a theoretical framework within the BCW - the Capability-Opportunity-Motivation-Behaviour Model (COM-B). The COM-B identifies the factors influencing whether an individual has the *Capability* (Psychological and Physical); the *Opportunity* (Physical and

Social) and the Motivation (Automatic and Reflective) to undertake the necessary actions required to achieve weight loss and maintenance 24. This may include environmental (e.g., physical, social) and individual factors (e.g., knowledge, emotions, motivation, behavioural regulation, cognitive skills). The Theoretical Domains Framework (TDF) consists of 14 domains within the COM-B that provide further details about the drivers of behaviour. Examples include *Belief about Capabilities,* *Intentions,* and *Optimism.* Identifying these factors is crucial in order to select the most suitable BCT techniques and digital features will be implemented in a given program.* BCTs are described as the core ingredients in a behaviour change intervention, known to be effective at helping someone to change a behaviour and form a new habit. In the next stage of the BCW, we identified appropriate *Intervention Functions* to include in the DBCI: *Education,* *Enablement,* *Environmental Restructuring,* and *Modelling.* We then utilised the Behaviour Change Technique Taxonomy (BCTTv1)25, a list of 93 possible BCTs, to identify suitable BCT*s. Other evidence-based psychological techniques from Cognitive Behavioural Therapy (CBT) and Acceptance and Commitment Therapy (ACT) were also included.

Evidence Base for Weight Management BCT Inclusion

A taxonomy of BCTs specifically relating to physical activity and healthy eating behaviours has been developed: the CALO-RE taxonomy26. This behaviour-specific 40-item taxonomy precedes the broader 93-item BCTv1 taxonomy25. The following BCTs from the BCTv1 taxonomy and CALO-RE taxonomy have been linked with more successful behavioural interventions, including physical activity and improved diet, for obese adults: *provision of instructions,* *relapse prevention,* *prompts and cues,* *goal setting,* *self-monitoring of the behaviour,* *barrier identification/problem solving,* and *plan for social support*27,28,29. These BCTs also link to the NICE guidelines for obesity behavioural strategies, highlighted above. The BCTs *self-monitoring,* *goal setting,* *instructions on performing health behaviour,* and feedback on performance* have also been associated with higher quality apps for improving health in adults30. As such, all of these BCTs were all included in the Allurion DBCI.

Health Coaching

BCTs can be delivered face-to-face or in digital format. For the purposes of this intervention, they will be delivered in digital form, but with real-person in-app support, in real time. The support, including BCT content, is delivered by a health coach. Health coaches are skilled in understanding the environmental, social and psychological barriers an individual might encounter in their attempts to lose weight; and what and how they can overcome these using various evidence-based strategies.

Allurion health coaches will provide participants with personalised and responsive support and assist with all aspects of the DBCI and BCT delivery. Health Coaching can help people to gain the ability, knowledge and efficacy to reach their own health and well-being goals31. Research has found that health coaching can be beneficial for improving health, particularly for obesity. A systematic review of trials exploring the effectiveness of health and wellness coaching for improving nutrition-related biomarkers and eating behaviours highlighted coaching as an *important strategy for the prevention and treatment of obesity and chronic disease across diverse populations*32. Delivery of health coaching via Tele-health and internet-based communication was also found to be effective. An observational clinical study using health coaching for weight loss in overweight/obese patients reported a mean loss of 7.24% initial weight after 12 months33. Including health coaching in a DBCI can provide flexible support for participants, allowing for the delivery of behaviour change strategies. This can be particularly beneficial for delivering behaviour change content as digital strategies have the potential to offer high fidelity of delivery34.

Health coaches will oversee the principal components of the DBCI: goal setting and action planning set by participants and reviewed weekly and support them in whatever BCT*s and other approaches are appropriate to support this, tailored to their needs. In particular, focus will be given to the following BCTs:

Weight Self-Monitoring

Self-monitoring or the systematic observation of one*s own*behaviour allows an individual to become more aware of the*extent to which he or she is engaging in a particular activity. Self-weighing alone has shown mixed effectiveness in weight loss35,36. Self-regulation combined with self-weighing appears to be more effective as the weight loss effect is due to a self-regulation mechanism, based on the hypothesis that self-monitoring triggers self-regulation. Self-regulation*is the ability to understand and manage your behaviour and your reactions to feelings and things happening around you37. It includes being able to regulate*reactions to emotions like frustration with lack of weight loss and then to put in place goal actions to reach the goal of losing weight. Therefore, alongside weight monitoring, participants will be supported by the health coach to utilize skills in self-regulation. In this context, self-regulation occurs in iterative cycles:

Contextualizing the weight with previous measurements and goals, which provides,

An opportunity to reflect on previous behaviour and reinforce successful actions, enabling,

The planning of actions to reach the goal,

Followed by performance of planned actions.

This cycle of processes allows for experimentation with different weight loss techniques (weight loss actions), helping the user to build a personal portfolio of effective and sustainable strategies. The Allurion DBCI is underpinned by the evidence-base, including the PREVAIL trial3,38. In this trial, the intervention group weighed themselves daily, tracked their weight in an app and then selected a daily evidence-based weight loss action from a menu of options. Participants completed daily and weekly questionnaires to prompt action planning, reflection and evaluation of actions. The control group was only asked to weigh themselves daily. Results found a mean weight loss of -4.2kg compared to -1.0kg in the control (-3.2kg difference, 95% CI: -4.49, -1.92) at 8 weeks. They also found high adherence rates and positive intervention ratings which demonstrated that the intervention was feasible and acceptable to participants. The Allurion DBCI will include psychological weight loss actions in addition to those similar to the PREVAIL trial.

Another recent study demonstrated that consistency of self*weighing may be more important than total frequency for preventing weight regain after the end of a weight*loss program. Results found that self*weighing for >=6 days/week may be necessary to promote successful weight*loss maintenance39. Therefore, promoting daily weight self-monitoring, using the Allurion Scale, will be a goal for trial participants.

Physical Activity and Sleep Self-Monitoring

Guidelines for adults in the UK recommend approximately 150 minutes of moderate exercise training, broadly defined as anything that raises the heartbeat, or 75 minutes of vigorous activity, such as running, per week40. Similarly, the Dutch Physical Activity Guidelines for adults recommend 150 minutes of weekly moderate exercise41. A review of physical activity interventions for weight loss demonstrated that following minimum recommendations may produce modest (0.5-3%) but not clinically significant weight loss (>= 5%); however, following guidelines may improve other clinical indicators, such as reductions in waist circumference and body fat42. Increasing the intensity and duration of exercise can result in additional weight loss43.

As the effects of intragastric balloons are only temporary, it is important that use of such devices is combined with both lifestyle and behavioural interventions and physical activity. This will aid long-term weight maintenance once the balloon has been removed or deflated44. For this study, emphasising

the importance of physical activity, monitoring of dietary intake and encouraging participants to maintain and self-report levels of physical activity through the app will be important steps for the health coaches in supporting participants to build the skills and efficacy to maintain weight loss and prevent future weight gain.

Physical activity tracking and planning are key DBCI features related to self-monitoring of behaviour and progress. It is also important to track sleep as healthy sleep, in terms of quality and duration, has been linked to lower body weight and may help to assist in sustaining weight loss following bariatric surgery45. Maintaining a consistent time of sleep onset may also be beneficial for weight loss management46. In this study, this type of tracking will be automated and facilitated by a physical activity and sleep sensor/tracker i.e., the Allurion Health Tracker (Watch). Health Tracker feedback will be personalised by an Allurion health coach based on user activity and sleep levels in relation to recommended and personalised goal setting. Participants in the study will be asked to wear their Allurion Health Tracker (Watch) at all times so that their sleep levels can be monitored by the health coach.

Dietary Self-Monitoring

For weight loss, self-monitoring usually involves tracking food and drink consumption47. By tracking meals via an established app, we will support users to be able to quickly identify a behaviour that may have positive or negative effects on the success or failure to meet their set goals.*Frequent tracking of food (even though people typically underestimate their dietary intake by around 18%) is associated with increased weight loss. A systematic review exploring the role of self-monitoring in weight loss found that weight loss was significantly higher in participants who consistently returned completed dietary self-monitoring logs. While it is unrealistic to expect participants to track all food eaten, recording foods consumed at least 75% of the time is a reasonable goal for self-monitoring intake and more likely to result in weight loss48. Encouraging participants of weight loss interventions to self-monitor their dietary intake is also likely to lead to positive behaviour change which can help to maintain long term weight maintenance47.

Social Support

Digital social support can include communities or social networks - message boards, user blogs, challenges, forums, closed groups (e.g., Facebook), group chats (e.g., WhatsApp), celebration walls, etc. The evidence shows that engagement with social network tools is correlated with longer engagement times. In addition, increasing social embeddedness (no. of *friends*) has been associated with greater weight loss. Social support is included as a BCT in the

Behaviour Change Taxonomy (BCTTv1) and is a good predictor of success during weight maintenance. It has strong appeal to some people, via the ability to interact with other people going through similar experience, coupled with 24/7 availability49. Social support can be helpful, but it should not be the primary strategy used to motivate health behaviour change and therefore is just one of a number of key BCTs in the Allurion DBCI.

Conclusion

The Allurion, evidence-based DBCI, has been designed to support participants to modify their lifestyle behaviours. Sustained improvements in lifestyle behaviours have been shown to support weight loss and weight loss maintenance. This prospective, pilot study of the Allurion DBCI, will evaluate the acceptability and impact of a personalised DBCI, delivered alongside the non-digital Elipse Gastric Balloon System after-care support. To our knowledge, this will be the first real world evaluation of a DBCI offered to intragastric balloon patients. Positive findings from this translational research have the potential to support improved outcomes for prospective Elipse Gastric Balloon System patients.

Study objective

To determine DBCI acceptability by examining how participants respond to the intervention, their views, perceptions, thoughts, feelings, benefits and barriers.

To determine DBCI acceptability by examining Elipse providers views, perceptions, thoughts, feelings, benefits and barriers in relation to the impact of the DBCI on trial participants.

To evaluate DBCI impact on participants health and psychosocial outcomes including weight, body composition, physical activity, sleep, heart rate, dietary intake, quality of life and psychological outcomes*known to influence successful weight loss and maintenance. These include mood, anxiety, Health-related Quality of Life (QoL) and overall well-being; self-efficacy and ability to self-regulate emotions, thoughts and behaviours relating to weight management.

Study design

This study is a prospective, non-randomized, pilot study to test the impact of the Allurion Digital Behaviour Change Intervention in participants who have been treated with the Elipse Gastric Balloon System. The study consists of the following segments:

Screening and enrolment period (prior to or day of Elipse Gastric Balloon

System treatment)

All participants will take part in the Allurion DBCI for 6 months following study enrolment

All participants will complete a 6-month follow-up assessment after completion of the Allurion DBCI

The total study duration per participant including screening and enrolment is anticipated to be approximately 13 months.

Intervention

All participants will undergo standard treatment with the commercially available Elipse Gastric Balloon System in accordance with the approved Instructions for Use. The Elipse Gastric Balloon System treatment includes an initial medical, nutritional and lifestyle assessment to determine suitability. In appropriate cases, this is followed by placement of the balloon, followed by after-care support. Standard support typically includes symptom, dietary and lifestyle management from placement to 6 months, but does not include behavioural modification and BCTs.

All patients undergoing the Elipse Gastric Balloon System treatment are provided with the following as part of the standard treatment after-care:

Allurion*Scale - to measure their weight

Allurion Health Tracker Watch- to measure steps, exercise and sleep

Allurion Mobile App - to track and visualise scale and Watch data

Allurion nutritional education brochure

Allurion DBCI

This study will evaluate the impact of a personalised DBCI, delivered alongside the standard after-care treatment support currently provided to Elipse Gastric Balloon System patients. The Allurion DBCI is a multicomponent, theoretically driven, and evidence-based behavioural intervention. Health coaching (delivered via the Allurion Mobile App) will form the overarching mechanism with which the majority of the intervention will be delivered.

Health coaches will support Elipse patients from balloon placement until 6 months. Health coaches will guide participants to improve their lifestyle

behaviours using well accepted behaviour change techniques known to enhance outcomes in the obesity and weight management scientific literature. Allurion health coaching participant support includes:

Setting goals using SMART goal setting framework.

Agreeing an action plan to help achieve goals and choose weight and health related actions.

Weekly weight change progress review, feedback and problem solving.

Enhancing motivation and self-efficacy (using motivational interviewing12).

Social support and personalisation.

Providing tailored physical activity, nutrition and behaviour change content.

Psychological techniques offered as required to help support the development of coping strategies associated with mood and eating, mindful eating and recognising hunger and satiety, cravings and impulse control, environmental drivers of weight loss actions; and techniques to enhance sustained habit formation.

Weight self-monitoring and application of self-regulation techniques (facilitated by the health coach and delivered via the Allurion Scale and Mobile App)

Physical activity and sleep self-monitoring and application of self-regulation (facilitated by the health coach and delivered via the Allurion Health Tracker Watch and Mobile App)

Dietary self-monitoring and application of self-regulation (facilitated by the health coach and delivered via commercial app meal tracking)

Social support (private, moderated, online community)

Health coaches will check-in with participants via in-app messaging weekly to provide feedback on their progress, in relation to their weight change, physical activity and sleep data. This will include a revision of their goals and action plan to establish what worked and what didn*t, problem solve and amend the actions as necessary. Participants will have access to the health coach 7 days per week for brief questions and support.

In order for health coaches to effectively deliver the DBCI, participants will be requested to:

Download the Allurion digital app (link will be provided)*

Weigh themselves with the*Allurion*scale at least weekly (preferably daily)*

Wear the*Allurion*health tracker (watch) as often as possible during the study*

Work with the health coach for six months post IGB balloon placement.

Study burden and risks

There is minimal risk to participants involved in this study. Study participants will not undergo any investigational or additional medical procedures as part of this study. Treatment with the commercially available Elipse Gastric Balloon System will be conducted per the standard of care and is outside the scope of this protocol. Due to the in-depth health coaching, participants could become aware of a new medical condition by partaking in this study.

Participants will engage in a number behaviour change interventions including health coaching, health monitoring (i.e., weight, sleep, physical activity, diet, etc.), and social support. This may result in improved weight control, diet, physical activity, and/or sleep.

All data collected as part of this study will be either through the Allurion Mobile or Web App, Scale, Health Tracker or participant questionnaires and interviews, which presents a potential cybersecurity risk. However, all data will be transferred and stored in a secure database with adequate controls in place to ensure patient privacy including compliance with General Data Protection Regulation (GDPR).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Elipse Gastric Balloon System placement in accordance with the approved Indications for Use

Age 21 to 65 years of age

BMI >= 27

Weight < 180 kg

Owns an Android or Apple smart phone

Willing to download the Allurion App

Willing to wear the Allurion Health Tracker Watch for the duration of the study

Willing to use the Allurion Scale

Proficient in reading the English language

Exclusion criteria

Any condition contraindicated for the Elipse Gastric Balloon System as specified in the Instructions for Use

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-08-2021
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO

Date:	26-07-2021
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL78284.096.21